

4/07/99 4:33 pm

Notification Tracking Sheet

Bp number: 99-095-16n

App number: 99-254XRAB
Received: 4/05/99
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 5/05/99
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person: (b) (6), (b) (7)(C)
Parsed name: (b) (6), (b) (7)(C)
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway North
Address3:
Address4:
City/State/Zip: St. Louis, MO 63198
Telephone: (b) (6), (b) (7)(C)
Begin movement: 4/30/99
End movement: 4/29/00
Begin release: 4/30/99
End release: 4/29/00
Acre:
CBI status: CBI
Fax: 314-737-7085

- | | Initial | Date |
|--|----------|-------------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [ell] | [4/8/99] |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist | [XZH]* | [4/9/99]* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State | [B67] | [4/9/99]* fed X |
| 4. <input type="checkbox"/> State response | | |

	O/d	Loc	Site	Reg
Interstate	*Dest*	CA	*	*WR *
Interstate	*Dest*	MO	*	*SCR *
Interstate	*Orig*	CA	*	*WR *
Interstate	*Orig*	MO	*	*SCR *
Release	*	CA	*	1*WR *

- | | Initial | Date |
|--|---------|-----------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [ell] | [4/9/99] |
| 6. <input checked="" type="checkbox"/> Letter of acknowledgement/denial/withdraw | [bgs] | [5/3/99]* FAX |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [bgs] | [5/4/99] |

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID
99-254XRAB

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 20737

Mar 31, 1999

99-095-16n

1. USDA Reference Number

2. Applicant Reference Number

99-254XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

314-737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company
700 Chesterfield Village Pkwy N
St. Louis, MO 63198

4. Duration of Introduction

Interstate Movement and Release Apr 30, 1999 - Apr 29, 2000

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

glyphosate-tolerant

(b) (6), (b)

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Monsanto Reference ID
99-254XRAB

designation of transformed line: 25372, 25397, 25463

Constructs: PV-TXGT05

genotype:

Gene of Interest

- * Promoter: CMP3/I5 -- [(b) (4)] - CBI *CBI*
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2 or 21), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Gene of Interest

- * Promoter: CMoVa/I5 -- [(b) (4)] - CBI *CBI*
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2 or 21), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

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Monsanto Reference ID
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7. Mode of Transformation Particle Bombardment

8. Introduction Interstate Movement and Release

Up to 55 pounds of seed and plant material to each location. After harvest, up to 550 pounds of seed and plant material to be returned to each location.

ORIGIN: CA MO **DESTINATION:** CA MO

Ship From:

CA

(b) (4), Santa Cruz County, CA (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4) Santa Cruz
County, CA, (b) (6), (b) (7)(C), (b) (4)

(b) (4), Contra Costa County, CA (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4), Contra Costa
County, CA, (b) (6), (b) (7)(C), (b) (4)

MO

(b) (4) St. Louis County, MO (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4), St. Louis
County, MO, (b) (6), (b) (7)(C), (b) (4)

(b) (4), Louis County, MO (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4), St.
Louis County, MO, (b) (6), (b) (7)(C), (b) (4)

Ship To:

CA

CONFIDENTIAL

Monsanto Reference ID
99-254XRAB

* [REDACTED] (b) (4), Contra Costa County, CA (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4) [REDACTED] Contra
Costa County, CA, (b) (6), (b) (7)(C) U.S.A., (b) (6), (b) (7)(C), (b) (4)

* [REDACTED] (b) (4), Santa Cruz County, CA (b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4), Santa
Cruz County, CA, (b) (6), (b) (7)(C) U.S.A., (b) (6), (b) (7)(C), (b) (4)

MO

[REDACTED] (b) (4), St. Louis County, MO (b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)
[REDACTED] St. Louis County, MO, (b) (6), (b) (7)(C), (b) (4)

[REDACTED] (b) (4), St. Louis County, MO (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4) [REDACTED], St.
Louis County, MO (b) (6), (b) (7)(C), (b) (4)

Release Sites:

NUMBER OF STATES/TERRITORIES AND SITES:

CA (1)

CA

* [REDACTED] (b) (4) Santa Cruz County, CA acres.

RESPONSIBLE PERSON/RESEARCHER: [REDACTED] (b) (4),
Santa Cruz County, CA. Contact [REDACTED] (b) (6), (b) (7)(C), (b) (4)

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Monsanto Reference ID
99-254XRAB

MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company
Mar 31, 1999

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential concerns the description of the gene introduced into potatoes and/or the variety into which they were transformed. The gene description category includes the names and information about genes, promoters and expressed traits.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many person years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of high solid, insect, fungal, and virus resistant potatoes for more than 10 years, and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the person hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promotor region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this FOIA request, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the CBI Justification expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include Rhone-Poulenc, ICI, and Ciba-Geigy.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, And Expressed Traits

The release of information about the genes and promoters in the vectors will directly provide *competitors* with the knowledge of the *precise* genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the *competitors* will have access to the structure of the Monsanto products, with the consequences outlined above. Patents *for* the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity And Characteristics Of Donor Organism

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms for tomatoes has been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identity of Recipient Cultivars

Some of the potato cultivars are claimed as confidential because disclosure of the variety name would identify a confidential business partner which has not been publicly announced.

Identification of Items claimed as Confidential Business Information

Items claimed as CBI as so indicated in the text as follows: [CBI - Deleted]. A non-confidential copy of the application is also included with the confidential item enclosed in brackets, "[]", as labeled as CBI.

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CBI - DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198

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<http://www.monsanto.com>

Monsanto Reference ID
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Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 20737

Mar 31, 1999

99-095-16n

1. USDA Reference Number
2. Applicant Reference Number
3. Applicant/Responsible Party

99-254XRAB

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)

FAX 314-737-7085

Monsanto Company
700 Chesterfield Village Pkwy N
St. Louis, MO 63198

EEmail (b) (6), (b) (7)(C) @monsanto.com

4. Duration of Introduction

Interstate Movement and Release Apr 30, 1999 - Apr 29, 2000

5. Recipient Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: glyphosate-tolerant

(b) (6), (b) (7)(C)

CBI - DELETED

Monsanto Reference ID
99-254XRAB

designation of transformed line: 25372, 25397, 25463

Constructs: PV-TXGT05

genotype:

Gene of Interest

- * Promoter: CMP3/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2 or 21), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Gene of Interest

- * Promoter: CMoVa/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2 or 21), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI - DELETED

Monsanto Reference ID
99-254XRAB

7. **Mode of Transformation** Particle Bombardment

8. **Introduction** Interstate Movement and Release

Up to 55 pounds of seed and plant material to each location. After harvest, up to 550 pounds of seed and plant material to be returned to each location.

ORIGIN:

CA

MO

DESTINATION:

CA

MO

Ship From:

CA

(b) (4)

Santa Cruz County, CA (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4), Santa Cruz
County, CA, (b) (6), (b) (7)(C), (b) (4)

(b) (4)

, Contra Costa County, CA (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4), Contra Costa
County, CA, (b) (6), (b) (7)(C), (b) (4)

MO

(b) (4)

St. Louis County, MO (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4), St. Louis
County, MO, (b) (6), (b) (7)(C), (b) (4)

(b) (4)

St. Louis County, MO (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4), St.
Louis County, MO, (b) (6), (b) (7)(C), (b) (4)

Ship To:

CA

CBI - DELETED

Monsanto Reference ID
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* (b) (4), Contra Costa County, CA (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4), Contra
Costa County, CA, (b) (6), (b) (7)(C), (b) (4) U.S.A., (b) (6), (b) (7)(C), (b) (4)

* (b) (4) Santa Cruz County, CA (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4), Santa
Cruz County, CA, (b) (6), (b) (7)(C), (b) (4) U.S.A., (b) (6), (b) (7)(C), (b) (4)

MO

* (b) (4) St. Louis County, MO (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4), St. Louis County, MO, (b) (6), (b) (7)(C), (b) (4)

* (b) (4) St. Louis County, MO (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4), St.
Louis County, MO, (b) (6), (b) (7)(C), (b) (4)

Release Sites:

NUMBER OF STATES/TERRITORIES AND SITES:

CA (1)

CA

* (b) (4) Santa Cruz County, CA acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4)
Santa Cruz County, CA. Contact: (b) (6), (b) (7)(C), (b) (4)

MONSANTO

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CBI - DELETED

MONSANTO COMPANY

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ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID
99-254XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

Mar 31, 1999

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Mar 31, 1999

99-095-16n

1. USDA Reference Number

2. Applicant Reference Number

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3. Applicant/Responsible Party

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Phone

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FAX

314-737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Village Pkwy N

St. Louis, MO 63198

4. Duration of Introduction

Interstate Movement and Release

Apr 30, 1999 - Apr 29, 2000

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

glyphosate-tolerant

Bob White

CBI - DELETED

Monsanto Reference ID
99-254XRAB

designation of transformed line: 25372, 25397, 25463

Constructs: PV-TXGT05

genotype:

Gene of Interest

- * Promoter: CMP3/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2 or 21), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.
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Gene of Interest

- * Promoter: CMoVa/I5 -- [CBI Deleted]
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- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI - DELETED

Monsanto Reference ID
99-254XRAB

7. Mode of Transformation Particle Bombardment

8. Introduction Interstate Movement and Release

Up to 55 pounds of seed and plant material to each location. After harvest, up to 550 pounds of seed and plant material to be returned to each location.

ORIGIN:
CA

MO

DESTINATION:
CA

MO

Ship From:

CA

(b) (4)

Santa Cruz County, CA (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4) Santa Cruz
County, CA, (b) (6), (b) (7)(C), (b) (4)

(b) (4)

Contra Costa County, CA (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4) Contra Costa
County, CA, (b) (6), (b) (7)(C), (b) (4)

MO

(b) (4)

St. Louis County, MO (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4) St. Louis
County, MO, (b) (6), (b) (7)(C), (b) (4)

(b) (4)

St. Louis County, MO (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4) St.
Louis County, MO, (b) (6), (b) (7)(C), (b) (4)

Ship To:

CA

CBI - DELETED

Monsanto Reference ID
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* (b) (4) Contra Costa County, CA (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4), Contra
Costa County, CA, (b) (6), (b) (7)(C) U.S.A., (b) (6), (b) (7)(C), (b) (4)

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CONTACT: (b) (6), (b) (7)(C), (b) (4), Santa
Cruz County, CA, (b) (6), (b) (7)(C) U.S.A., (b) (6), (b) (7)(C), (b) (4)

MO

* (b) (4) St. Louis County, MO (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4)
(b) (6), (b) (7)(C), (b) (4) St. Louis County, MO, (b) (6), (b) (7)(C), (b) (4)

*] (b) (4) ,St. Louis County, MO (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4) St.
Louis County, MO, (b) (6), (b) (7)(C), (b) (4)

Release Sites:

NUMBER OF STATES/TERRITORIES AND SITES:

CA (1)

CA

* (b) (4) , Santa Cruz County, CA acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (6), (b) (7)(C), (b) (4)
Santa Cruz County, CA. Contact: (b) (6), (b) (7)(C), (b) (4)

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99-254XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

Mar 31, 1999

file copy

Ms. Barbara Hass, State Regulatory Official
California Department of Food and Agriculture
1220 N Street - Rm A-372
Sacramento, CA 95814

April 5, 1999

Dear Ms. Hass:

Enclosed is notification 99-095-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-095-16n	Applicant #:	99-254XRAB
Received:	April 5, 1999	Effective:	May 5, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA MO		
Release destination:	CA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012571

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

April 5, 1999

Dear Mr. Brown:

Enclosed is notification 99-095-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-095-16n	Applicant #:	99-254XRAB
Received:	April 5, 1999	Effective:	May 5, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA MO		
Release destination:	CA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012572



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Ms. Barbara Hass, State Regulatory Official
California Department of Food and Agriculture
1220 N Street - Rm A-372
Sacramento, CA 95814

April 5, 1999

Dear Ms. Hass:

Enclosed is notification 99-095-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-095-16n	Applicant #:	99-254XRAB
Received:	April 5, 1999	Effective:	May 5, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA MO		
Release destination:	CA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Barbara I. Hass (916) 654-1017

Signature: (b) (6), (b) (7)(C)

Date: April 14, 1999

State: California

OR120018_BR_012573

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4-15-99



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MO 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

April 5, 1999

Dear Mr. Brown:

Enclosed is notification 99-095-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-095-16n	Applicant #:	99-254XRAB
Received:	April 5, 1999	Effective:	May 5, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA MO		
Release destination:	CA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: (b) (6), (b) (7)(C)

Date: 4/13/99

State: MO



May 3, 1999

(b) (6), (b) (7)(C)
Monsanto Company
700 Chesterfield Parkway N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C) :

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3 (c), effective on or after May 5, 1999.

Interstate movement and release
Notification no. 99-095-16n (99-254XRAB)
Regulated article - Wheat
Destination(s) - California, Missouri

You must comply with the performance standards as stated in 7 CFR 340.3 (c). In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Official(s), and the Regional Program Manager(s), (Biotechnology).

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

CC:
B. Hass, California Dept. of Food and Agric., Sacramento, CA
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
R. Stoaks, PPQ, WR, Sacramento, CA
D. DeWeese, PPQ, SCR, Brownsville, TX
File number 99-095-16n

OR120018_BR_012575

Confirmation Report-Memory Send

Time : 05-06-99 04:50pm
Tel line 1 : +3017348910
Tel line 2 : +
Name : USDA

Job number : 884
Date : 05-06 04:49pm
To : 913147377085
Document Pages : 02
Start time : 05-06 04:49pm
End time : 05-06 04:50pm
Pages sent : 02
Job number : 884

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

May 6, 1999

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear

(b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3 (c), effective on or after May 6, 1999.

Interstate movement and Release
Notification no. 99-075-03a (99-225XRAB)
Regulated article - Cotton
Destinations - Alabama, Missouri, Mississippi, North Carolina, Texas

You must comply with the performance standards as stated in 7 CFR 340.3 (c). In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

The State of Mississippi require cotton seed moving from a Pink Bollworm regulated area move under a state or federal certificate.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:
G. Karr, Alabama Dept. of Agric. and Industries, Montgomery, AL
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
E. Dyess, Mississippi Dept. of Agric. and Commerce, Mississippi State, MS
S. Baker, North Carolina Dept. of Agric., Raleigh, NC
T. Mitchell, Texas Dept. of Agric., Austin, TX
S. Wood, PPQ, SER, Raleigh, NC
D. Deweese, PPQ, SCK, Brownsville, TX



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_012576

1999 Wheat Field Test Report
USDA # 99-095-16n Monsanto # 99-254XRAB

(b) (6), (b) (7)(C)

October 3, 2000

Monsanto Company

Location

(b) (4)

County

Santa Cruz

State

CA

Santa Cruz, CA

Planting Date: May 17, 1999

Harvest Date: June 21, 1999

Destruct Date (if not harvested): October 5, 1999 wheat stubble removed

Vector Constructs/Line Numbers Planted: (b) (4)

Purpose of Field Trial: (b) (4)

Field Monitoring for Disease Susceptibility: (b) (4)

Field Monitoring for Insect Susceptibility: (b) (4)

Field Monitoring for Plant Growth Characteristics: (b) (4)

Field Monitoring for Weediness Characteristics: (b) (4)

Field Monitoring for Plant Stand: (b) (4)

Disposition of the seed: (b) (4)

Results: (b) (4)

MONSANTO

Food • Health • Hope



December 8, 2000

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

Ms. Dianne Hatmaker
Animal and Plant Health Inspection Services
Biotechnology and Scientific Services
4700 River Road, Unit 147
Riverdale, MD

Dear Ms. Hatmaker;

Field releases for the following USDA wheat notifications have been completed and we are now submitting final reports as required. Please find reports for:

<u>USDA Number</u>	<u>Monsanto number</u>
98-333-06n	98-040XR
98-035-04n	98-042XR
98-224-03n	98-313XR
98-229-11n	98-324XRAB
98-261-03n	98-382XRAB
98-261-04n	98-383XRAB
99-039-13n	99-053XRAB
99-039-14n	99-054XRAB
99-047-09n	99-011XR
99-047-11n	99-013XR
99-048-16n	99-094XRA
99-064-15n	99-148XR
99-064-18n	99-144XR
99-092-04n	99-240XRAB
99-092-05n	99-241XRAB
99-095-16n	99-254XRAB
99-105-03n	99-256XRAB
99-126-12n	99-410XRAB
99-130-03n	99-474XRAB

OR120018_BR_012578

MONSANTO

Food • Health • Hope



If you have any questions concerning these reports, please do not hesitate to
contact me at (b) (6), (b) (7)(C)

Sincerely,

(b) (6), (b) (7)(C)

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

4/19/99 11:01 am

Notification Tracking Sheet

Bp number: 99-105-03n

App number: 99-256XRAB
Received: 4/15/99
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 5/15/99
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person: (b) (6), (b) (7)(C)
Parsed name: (b) (6), (b) (7)(C) (b) (6), (b) (7)(C)
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway North
Address3:
Address4:
City/State/Zip: St. Louis, MO 63198
Telephone: (b) (6), (b) (7)(C)
Begin movement: 4/30/99
End movement: 4/29/00
Begin release: 4/30/99
End release: 4/29/00
Acre: 2.00
CBI status: CBI
Fax: 314-737-7085

- | | Initial | Date |
|--|-----------------|--------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [<i>hli</i>] | [4/16/99] |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist | [<i>smk</i>]* | [4/19/99]* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State | [<i>Bls</i>] | [4/21/99]* |
| 4. <input type="checkbox"/> State response | | |

	O/d	Loc	Site	Reg
Interstate	*Dest*	MO	*	*SCR *
Interstate	*Dest*	MT	*	*WR *
Interstate	*Orig*	MO	*	*SCR *
Interstate	*Orig*	MT	*	*WR *
Release	*	*MT	*	1*WR *

- | | | |
|--|----------------|--------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [<i>hli</i>] | [4/19/99] |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw | [<i>hgs</i>] | [5/10/99]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [<i>hgs</i>] | [5/11/99] |

5/11/99 Hand-let. by

(b) (6), (b) (7)(C)

MONSANTO

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CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

99-256XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 20737

Mar 31, 1999

99-105-03n

1. USDA Reference Number

2. Applicant Reference Number

99-256XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C) 5

(b) (6), (b) (7)(C)

FAX

314-737-7085

(b) (6), (b) (7)(C)

Monsanto Company

EMail

(b) (6), (b) (7)(C) @monsanto.com

700 Chesterfield Village Pkwy N

St. Louis, MO 63198

4. Duration of Introduction

Interstate Movement and Release

Apr 30, 1999 - Apr 29, 2000

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

glyphosate-tolerant

Cultivar(s)/Variety: Bobwhite

CONFIDENTIAL

Monsanto Reference ID
99-256XRAB

designation of transformed line: TA-S1087, TA-S1102, TA-S1711

Constructs: PV-TXGT10

genotype:

Gene of Interest

* Promoter: CMoVa/I2 -- [REDACTED] (b) (4)

CBI

] - CBI

* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2 or 21), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Gene of Interest

* Promoter: CMP3/I5 -- [REDACTED] (b) (4)

CBI

- CBI

* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2 or 21), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID
99-256XRAB

designation of transformed line: 35710, 35845

Constructs: PV-TXGT12

genotype:

Gene of Interest

* Promoter: MP4 -- [REDACTED] (b) (4) CBI
[REDACTED]] - CBI

* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2 or 21), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

* Terminator: M1 -- [REDACTED] (b) (4) CBI
[REDACTED] - CBI

Gene of Interest

* Promoter: CMP 3/I5 -- [REDACTED] (b) (4) CBI
[REDACTED]] - CBI

* Gene: CTP7-CP4 -- [REDACTED] (b) (4) CBI
[REDACTED] - CBI

* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID
99-256XRAB

designation of transformed line: TA-S537

Constructs: PV-TXGT13

genotype:

Gene of Interest

* Promoter: MP4 -- [REDACTED] (b) (4)

CBI

[REDACTED] - CBI

* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2 or 21), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

* Terminator: M1 3' -- [REDACTED] (b) (4)

CBI

CBI

CONFIDENTIAL

Monsanto Reference ID
99-256XRAB

designation of transformed line: TA-S2744, TA-S2747

Constructs: PV-TXGT15

genotype:

Gene of Interest

- * Promoter: CMP 3/I5 -- [REDACTED] (b) (4)] - CBI *CBI*
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2 or 21), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Gene of Interest

- * Promoter: MP4 -- [REDACTED] (b) (4)] - CBI *CBI*
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2 or 21), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: M1 3' -- [REDACTED] (b) (4)] - CBI *CBI*

CONFIDENTIAL

Monsanto Reference ID
99-256XRAB

7. **Mode of Transformation** Disarmed Agrobacterium tumefaciens
8. **Introduction** Interstate Movement and Release

Up to 80 pounds of wheat seed to each location. After harvest, up to 800 pounds to be returned to each location.

ORIGIN: MO MT **DESTINATION:** MO MT

Ship From:

MO

* [REDACTED] (b) (4), St. Louis County, MO (b) (4)

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C), St. Louis County, MO, (b) (4), (b) (6), (b) (7)(C)

MT

* [REDACTED] (b) (4), (b) (6), (b) (7)(C), Pondera County, MT

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C), Pondera County, MT, (b) (4), (b) (6), (b) (7)(C)

Ship To:

MO

[REDACTED] (b) (4), St. Louis County, MO (b) (4)

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C), St. Louis County, MO, (b) (4), (b) (6), (b) (7)(C)

MT

* [REDACTED] (b) (4), (b) (6), (b) (7)(C), Pondera County, MT

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C), Pondera County, MT, (b) (4), (b) (6), (b) (7)(C)

Release Sites:

CONFIDENTIAL

Monsanto Reference ID
99-256XRAB

NUMBER OF STATES/TERRITORIES AND SITES:

MT (1)

MT

* Doug Ryerson Farm, Pondera County, MT up to 2 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C) Pondera
County, MT. Contact: (b) (4), (b) (6), (b) (7)(C)

MONSANTO

Food · Health · Hope



CONFIDENTIAL

Monsanto Reference ID
99-256XRAB

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

Mar 31, 1999

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

Monsanto Reference ID
99-256XRAB

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 20737

Mar 31, 1999

99-105-03n

1. USDA Reference Number
2. Applicant Reference Number
3. Applicant/Responsible Party

99-256XRAB

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)

FAX 314-737-7085

EMail (b) (6), (b) (7)(C)@monsanto.com

Monsanto Company
700 Chesterfield Village Pkwy N
St. Louis, MO 63198

4. Duration of Introduction

Interstate Movement and Release Apr 30, 1999 - Apr 29, 2000

5. Recipient Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT
Phenotype: glyphosate-tolerant
Cultivar(s)/Variety: Bobwhite

CBI - DELETED

Monsanto Reference ID
99-256XRAB

designation of transformed line: TA-S1087, TA-S1102, TA-S1711

Constructs: PV-TXGT10

genotype:

Gene of Interest

- * Promoter: CMoVa/I2 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2 or 21), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Gene of Interest

- * Promoter: CMP3/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2 or 21), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI - DELETED

Monsanto Reference ID
99-256XRAB

designation of transformed line: 35710, 35845

Constructs: PV-TXGT12

genotype:

Gene of Interest

- * Promoter: MP4 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2 or 21), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.
- * Terminator: M1 -- [CBI Deleted]

Gene of Interest

- * Promoter: CMP 3/I5 -- [CBI Deleted]
- * Gene: CTP7-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI - DELETED

Monsanto Reference ID
99-256XRAB

designation of transformed line: TA-S537

Constructs: PV-TXGT13

genotype:

Gene of Interest

- * Promoter: MP4 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2 or 21), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: M1 3' -- [CBI Deleted]

CBI - DELETED

Monsanto Reference ID
99-256XRAB

designation of transformed line: TA-S2744, TA-S2747

Constructs: PV-TXGT15

genotype:

Gene of Interest

- * Promoter: CMP 3/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2 or 21), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Gene of Interest

- * Promoter: MP4 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2 or 21), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: M1 3' -- [CBI Deleted]

CBI - DELETED

Monsanto Reference ID
99-256XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Up to 80 pounds of wheat seed to each location. After harvest, up to 800 pounds to be returned to each location.

ORIGIN:		DESTINATION:	
MO	MT	MO	MT

Ship From:

MO

* (b) (4) St. Louis County, MO (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4) St.
Louis County, MO, (b) (6), (b) (7)(C), (b) (4)

MT

(b) (6), (b) (7)(C), (b) (4) Great Falls, Pondera County, MT

CONTACT: (b) (6), (b) (7)(C), (b) (4) Pondera County,
MT, (b) (6), (b) (7)(C), (b) (4)

Ship To:

MO

* (b) (4) St. Louis County, MO (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4)
St. Louis County, MO, (b) (6), (b) (7)(C), (b) (4)

MT

(b) (6), (b) (7)(C), (b) (4) Pondera County, MT

CONTACT: (b) (6), (b) (7)(C), (b) (4) Pondera
County, MT, (b) (6), (b) (7)(C), (b) (4)

Release Sites:

CBI - DELETED

Monsanto Reference ID
99-256XRAB

NUMBER OF STATES/TERRITORIES AND SITES:

MT (1)

MT

* (b) (6), (b) (7)(C), (b) (4), Pondera County, MT up to 2 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (6), (b) (7)(C), (b) (4) Pondera
County, MT. Contact: (b) (6), (b) (7)(C), (b) (4)

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID
99-256XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

Mar 31, 1999

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

St. Louis, Missouri 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID
99-256XRAB

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 20737

Mar 31, 1999

99-105-03n

1. USDA Reference Number
2. Applicant Reference Number
3. Applicant/Responsible Party

99-256XRAB

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C)

FAX

314-737-7085

(b) (6), (b) (7)(C)

Monsanto Company

EMail

(b) (6), (b) (7)(C)@monsanto.com

700 Chesterfield Village Pkwy N

St. Louis, MO 63198

4. Duration of Introduction

Interstate Movement and Release

Apr 30, 1999 - Apr 29, 2000

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: glyphosate-tolerant

Cultivar(s)/Variety: Bobwhite

CBI - DELETED

Monsanto Reference ID
99-256XRAB

designation of transformed line: TA-S1087, TA-S1102, TA-S1711

Constructs: PV-TXGT10

genotype:

Gene of Interest

- * Promoter: CMoVa/12 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2 or 21), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Gene of Interest

- * Promoter: CMP3/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2 or 21), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI - DELETED

Monsanto Reference ID
99-256XRAB

designation of transformed line: 35710, 35845

Constructs: PV-TXGT12

genotype:

Gene of Interest

- * Promoter: MP4 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2 or 21), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: M1 -- [CBI Deleted]

Gene of Interest

- * Promoter: CMP 3/I5 -- [CBI Deleted]
- * Gene: CTP7-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI - DELETED

Monsanto Reference ID
99-256XRAB

designation of transformed line: TA-S537

Constructs: PV-TXGT13

genotype:

Gene of Interest

- * Promoter: MP4 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2 or 21), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: M1 3' -- [CBI Deleted]

CBI - DELETED

Monsanto Reference ID
99-256XRAB

designation of transformed line: TA-S2744, TA-S2747

Constructs: PV-TXGT15

genotype:

Gene of Interest

- * Promoter: CMP 3/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2 or 21), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Gene of Interest

- * Promoter: MP4 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2 or 21), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: M1 3' -- [CBI Deleted]

CBI - DELETED

Monsanto Reference ID
99-256XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Up to 80 pounds of wheat seed to each location. After harvest, up to 800 pounds to be returned to each location.

ORIGIN: MO MT DESTINATION: MO MT

Ship From:

MO

(b) (4) St. Louis County, MO 63198

CONTACT: (b) (6), (b) (7)(C), (b) (4) St.
Louis County, MO, (b) (6), (b) (7)(C), (b) (4)

MT

(b) (6), (b) (7)(C), (b) (4) Pondera County, MT

CONTACT: (b) (6), (b) (7)(C), (b) (4) Pondera County,
MT, (b) (6), (b) (7)(C), (b) (4)

Ship To:

MO

* 1 (b) (4) St. Louis County, MO 63198

CONTACT: (b) (6), (b) (7)(C), (b) (4)
St. Louis County, MO, (b) (6), (b) (7)(C), (b) (4)

MT

* (b) (6), (b) (7)(C), (b) (4) Pondera County, MT

CONTACT: (b) (6), (b) (7)(C), (b) (4) Pondera
County, MT, (b) (6), (b) (7)(C), (b) (4)

Release Sites:

CBI - DELETED

Monsanto Reference ID
99-256XRAB

NUMBER OF STATES/TERRITORIES AND SITES:

MT (1)

MT

* (b) (6), (b) (7)(C), (b) (4) Pondera County, MT up to 2 acres.

RESPONSIBLE PERSON/RESEARCHER (b) (6), (b) (7)(C), (b) (4) [REDACTED], Pondera
County, MT. Contact: (b) (6), (b) (7)(C), (b) (4) [REDACTED]

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Monsanto Reference ID
99-256XRAB

MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

Mar 31, 1999

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

April 15, 1999

Dear Mr. Brown:

Enclosed is notification 99-105-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-105-03n	Applicant #:	99-256XRAB
Received:	April 15, 1999	Effective:	May 15, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO MT		
Release destination:	MT		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012609

file copy

Dr. Gary Gingery, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

April 15, 1999

Dear Dr. Gingery:

Enclosed is notification 99-105-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-105-03n	Applicant #:	99-256XRAB
Received:	April 15, 1999	Effective:	May 15, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO MT		
Release destination:	MT		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012610



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

April 15, 1999

Dear Mr. Brown:

Enclosed is notification 99-105-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-105-03n	Applicant #:	99-256XRAB
Received:	April 15, 1999	Effective:	May 15, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO MT		
Release destination:	MT		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: (b) (6), (b) (7)(C)

Date: 4/26/99

State: MO





United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Dr. Gary Gingery, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

April 15, 1999

Dear Dr. Gingery:

Enclosed is notification 99-105-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 99-105-03n

Applicant #: 99-256XRAB

Received: April 15, 1999

Effective: May 15, 1999

Institution: Monsanto

Recipient: Wheat

Interstate destination: MO MT

Release destination: MT

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

✓

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Lori M. Witham

Signature: (b) (6), (b) (7)(C)

Date: April 22, 1999

State: Montana

OR120018_BR_012612

An Equal Opportunity Employer

4/23/99

May 11, 1999

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Village Parkway N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C) :

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3 (c), effective on or after May 15, 1999.

Interstate movement and release
Notification no. 99-105-03n (99-256XRAB)
Regulated article - Wheat
Destination(s) - Missouri, Montana

You must comply with the performance standards as stated in 7 CFR 340.3 (c). In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Official(s), and the Regional Program Manager(s), (Biotechnology).

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

CC:

M. Brown, Missouri Dept. of Agric., Jefferson City, MO
G. Gingery, Montana Dept. of Agric., Helena, MT
D. DeWeese, PPQ, SCR, Brownsville, TX
R. Stoaks, PPQ, WR, Sacramento, CA
File number 99-105-03n

OR120018_BR_012613

MONSANTO

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December 8, 2000

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

Ms. Dianne Hatmaker
Animal and Plant Health Inspection Services
Biotechnology and Scientific Services
4700 River Road, Unit 147
Riverdale, MD

Dear Ms. Hatmaker;

Field releases for the following USDA wheat notifications have been completed and we are now submitting final reports as required. Please find reports for:

<u>USDA Number</u>	<u>Monsanto number</u>
98-333-06n	98-040XR
98-035-04n	98-042XR
98-224-03n	98-313XR
98-229-11n	98-324XRAB
98-261-03n	98-382XRAB
98-261-04n	98-383XRAB
99-039-13n	99-053XRAB
99-039-14n	99-054XRAB
99-047-09n	99-011XR
99-047-11n	99-013XR
99-048-16n	99-094XRA
99-064-15n	99-148XR
99-064-18n	99-144XR
99-092-04n	99-240XRAB
99-092-05n	99-241XRAB
99-095-16n	99-254XRAB
99-105-03n	99-256XRAB
99-126-12n	99-410XRAB
99-130-03n	99-474XRAB

OR120018_BR_012614

MONSANTO

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If you have any questions concerning these reports, please do not hesitate to contact me at (b) (6), (b) (7)(C).

Sincerely,

(b) (6), (b) (7)(C)

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63108
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

1999 Wheat Field Test Report
USDA # 99-105-03n Monsanto # 99-256XRAB
(b) (6), (b) (7)(C)
October 2, 2000

Monsanto Company

Location

(b) (4)

County

Pondera

State

MT

Pondera, MT

Planting Date: May 17, 1999

Harvest Date: August 26, 1999

Vector Constructs/Line Numbers Planted:

(b) (4)

Purpose of Field Trial:

(b) (4)

Field Monitoring for Disease Susceptibility:

(b) (4)

Field Monitoring for Insect Susceptibility:

(b) (4)

Field Monitoring for Plant Growth Characteristics:

(b) (4)

Field Monitoring for Weediness Characteristics:

(b) (4)

Disposition of the seed:

(b) (4)

9/09/99 7:56 am

Notification Tracking Sheet

=====

Bp number: 99-251-03n

=====

App number: 99-675XRAB
Received: 9/08/99
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 10/08/99
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person: (b) (6), (b) (7)(C)
Parsed name: (b) (6), (b) (7)(C)
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: (b) (6), (b) (7)(C)
Begin movement: 10/07/99
End movement: 10/06/00
Begin release: 10/07/99
End release: 10/06/00
Acre: 3.00
CBI status: CBI
Fax: 636-737-7085

- | | Initial | Date |
|--|---------|-------------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [apd] | [9/9/99] |
| 2. <input type="checkbox"/> Review by biotechnologist | [JN]* | []* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State | [BLS] | [9/9/99]* fedex |
| 4. <input type="checkbox"/> State response | | |

	O/d	Loc	Site	Reg		
Interstate	*Dest*	CO	*	*WR	*	[] []
Interstate	*Dest*	MT	*	*WR	*	[] []
Interstate	*Dest*	WA	*	*WR	*	[] []
Interstate	*Orig*	CO	*	*WR	*	
Interstate	*Orig*	MT	*	*WR	*	
Interstate	*Orig*	WA	*	*WR	*	
Release	*	CO	*	1*WR	*	[] []
Release	*	MT	*	1*WR	*	[] []
Release	*	WA	*	1*WR	*	[] []

- | | | |
|--|---------|--------------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [apd] | [9/9/99] |
| 6. <input checked="" type="checkbox"/> Letter of acknowledgement/denial/withdraw | [bgs] | [9/23/99]* fedex |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [bgs] | [9/23/99] |

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CONFIDENTIAL

MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

Monsanto Reference ID
99-675XRAB

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 20737

Sep 07, 1999

99-251-03n

1. USDA Reference Number
2. Applicant Reference Number
3. Applicant/Responsible Party

99-675XRAB

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)

FAX 636/737-7085

Email (b) (6), (b) (7)(C)@monsanto.com

Monsanto Company
700 Cheserfield Parkway North
St. Louis, MO

4. Duration of Introduction

Interstate Movement and Release Oct 07, 1999 - Oct 06, 2000

5. Recipient Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT
Phenotype: glyphosate tolerant
Cultivar/Varities Bobwhite and B1175 or B1183

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Monsanto Reference ID
99-675XRAB

designation of transformed line: 25372, 25397

Constructs: PV-TXGT05

genotype:

Gene of Interest

* Promoter: CMP3/I5 -- (b) (4)
] - CBI

CBI

* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Gene of Interest

* Promoter: CMoVa/I5 -- (b) (4)
] - CBI

CBI

* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

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Monsanto Reference ID
99-675XRAB

- 7. Mode of Transformation** Particle Bombardment
8. Introduction Interstate Movement and Release

Ship up to 2200 pounds wheat seed before and after harvest

ORIGIN:		DESTINATION:	
CO	MT	CO	MT
WA		WA	

Ship From:

CO

(b) (4), Yuma County, CO

CONTACT: (b) (4), (b) (6), (b) (7)(C) Yuma County, CO

MT

(b) (4), Cascade County, MT 59404

CONTACT: (b) (4), (b) (6), (b) (7)(C), Cascade County,
MT, (b) (4), (b) (6), (b) (7)(C)

WA

(b) (4), Walla Walla County, WA 99362

CONTACT: (b) (4), (b) (6), (b) (7)(C), Benton County, WA,
(b) (4), (b) (6), (b) (7)(C)

Ship To:

CO

* (b) (4), Yuma County, CO

CONTACT: (b) (4), (b) (6), (b) (7)(C), Yuma County, CO

CONFIDENTIAL

Monsanto Reference ID
99-675XRAB

MT

* (b) (4), Cascade County, MT (b) (4)

CONTACT: (b) (4), (b) (6), (b) (7)(C), Cascade County,
MT, (b) (4), (b) (6), (b) (7)(C)

WA

(b) (4), Walla Walla County, WA (b) (4)

CONTACT (b) (4), (b) (6), (b) (7)(C),
Walla Walla County, WA, (b) (4), (b) (6), (b) (7)(C)

Release Sites:

NUMBER OF STATES/TERRITORIES AND SITES:

CO (1) MT (1) WA (1)

CO

* (b) (4), Yuma County, CO up to 1 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C), Yuma County,
CO. Contact: (b) (4), (b) (6), (b) (7)(C)

MT

* (b) (4) Cascade County, MT up to 1 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C) Cascade
County, MT. Contact: (b) (4), (b) (6), (b) (7)(C)

WA

* (b) (4), Walla Walla County, WA up to 1 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
Walla Walla County, WA. Contact: (b) (4), (b) (6), (b) (7)(C)

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Monsanto Reference ID
99-675XRAB

CONFIDENTIAL
MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company
Sep 07, 1999

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential concerns the description of the gene introduced into corn and/or the variety into which they were transformed. The gene description category includes the names and information about genes, promoters and expressed traits.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many person years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of high solid, insect, fungal, and virus resistant crops for more than 10 years, and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the person hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this FOIA request, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the CBI Justification expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include Rhone-Poulenc, ICI, and Ciba-Geigy.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, And Expressed Traits

The release of information about the genes and promoters in the vectors will directly provide *competitors* with the knowledge of the *precise* genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the *competitors* will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity And Characteristics Of Donor Organism

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identity of Recipient Cultivars

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organism has been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification of Items claimed as Confidential Business Information

Items claimed as CBI as so indicated in the text as follows: [CBI - Deleted]. A non-confidential copy of the application is also included with the confidential item enclosed in brackets, "[]", as labeled as CBI.

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CBI - DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

http://www.monsanto.com

Monsanto Reference ID
99-675XRAB

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 20737

Sep 07, 1999

99-251-03n

1. USDA Reference Number

2. Applicant Reference Number

99-675XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company
700 Cheserfield Parkway North
St. Louis, MO

4. Duration of Introduction

Interstate Movement and Release

Oct 07, 1999 - Oct 06, 2000

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: glyphosate tolerant

Cultivar/Varieties Bobwhite and B1175 or B1183

CBI - DELETED

Monsanto Reference ID
99-675XRAB

designation of transformed line: 25372, 25397

Constructs: PV-TXGT05

genotype:

Gene of Interest

- * Promoter: CMP3/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Gene of Interest

- * Promoter: CMoVa/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
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CBI - DELETED

Monsanto Reference ID
99-675XRAB

- 7. Mode of Transformation** Particle Bombardment
8. Introduction Interstate Movement and Release

Ship up to 2200 pounds wheat seed before and after harvest

ORIGIN:		DESTINATION:	
CO	MT	CO	MT
WA		WA	

Ship From:

CO

* (b) (4) Yuma County, CO

CONTACT: (b) (6), (b) (7)(C), (b) (4) Yuma County, CO

MT

* (b) (4) Cascade County, MT 59404

CONTACT: (b) (6), (b) (7)(C), (b) (4) Cascade County,
MT, (b) (6), (b) (7)(C), (b) (4)

WA

* (b) (4) Walla Walla County, WA 99362

CONTACT: (b) (6), (b) (7)(C), (b) (4) Benton County, WA,
(b) (6), (b) (7)(C), (b) (4)

Ship To:

CO

* (b) (4) Yuma County, CO

CONTACT: (b) (6), (b) (7)(C), (b) (4) Yuma County, CO

CBI - DELETED

Monsanto Reference ID
99-675XRAB

MT

* (b) (4) , Cascade County, MT (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4) , Cascade County,
MT, (b) (6), (b) (7)(C), (b) (4)

WA

* (b) (4) Walla Walla County, WA (b) (4)

CONTACT (b) (6), (b) (7)(C), (b) (4)
Walla Walla County, WA, (b) (6), (b) (7)(C), (b) (4)

Release Sites:

NUMBER OF STATES/TERRITORIES AND SITES:

CO (1) MT (1) WA (1)

CO

* (b) (4) , Yuma County, CO up to 1 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (6), (b) (7)(C), (b) (4) Yuma County,
CO. Contact: (b) (6), (b) (7)(C), (b) (4)

MT

* (b) (4) , Cascade County, MT up to 1 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (6), (b) (7)(C), (b) (4) , Cascade
County, MT. Contact: (b) (6), (b) (7)(C), (b) (4)

WA

* (b) (4) , Walla Walla County, WA up to 1 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (6), (b) (7)(C), (b) (4)
Walla Walla County, WA. Contact: (b) (6), (b) (7)(C), (b) (4)

MONSANTO

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CBI - DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID
99-675XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

Sep 07, 1999

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4700 River Rd.
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Sep 07, 1999

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1. USDA Reference Number
2. Applicant Reference Number
3. Applicant/Responsible Party

99-675XRAB

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C)

FAX

636/737-7085

Monsanto Company

E-Mail

(b) (6), (b) (7)(C) @monsanto.com

700 Cheserfield Parkway North

St. Louis, MO

4. Duration of Introduction

Interstate Movement and Release

Oct 07, 1999 - Oct 06, 2000

5. Recipient Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: glyphosate tolerant

Cultivar/Varities Bobwhite and B1175 or B1183

Monsanto Reference ID
99-675XRAB

designation of transformed line: 25372, 25397

Constructs: PV-TXGT05

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CBI - DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

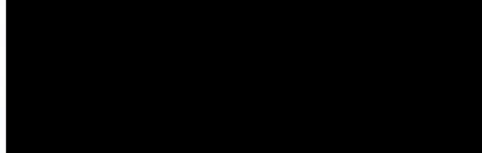
<http://www.monsanto.com>

Monsanto Reference ID
99-675XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

Sep 07, 1999

file copy

Mr. Mitch Yergert
Colorado Department of Agriculture
700 Kipling Street - Suite 4000
Lakewood, CO 80215-5894

September 9, 1999

Dear Mr. Yergert:

Enclosed is notification 99-251-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Ep number	99-251-03n	Applicant #:	99-675XRAB
Received:	September 8, 1999	Effective:	October 8, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO MT WA		
Release destination:	CO MT WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012634

file copy

Dr. Gary Gingery, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

September 9, 1999

Dear Dr. Gingery:

Enclosed is notification 99-251-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-251-03n	Applicant #:	99-675XRAB
Received:	September 8, 1999	Effective:	October 8, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO MT WA		
Release destination:	CO MT WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012635

file copy

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

September 9, 1999

Dear Mr. Wessels:

Enclosed is notification 99-251-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-251-03n	Applicant #:	99-675XRAB
Received:	September 8, 1999	Effective:	October 8, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO MT WA		
Release destination:	CO MT WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012636



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Mitch Yergert
Colorado Department of Agriculture
700 Kipling Street - Suite 4000
Lakewood, CO 80215-5894

September 9, 1999

Dear Mr. Yergert:

Enclosed is notification 99-251-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Ep number	99-251-03n	Applicant #:	99-675XRAB
Received:	September 8, 1999	Effective:	October 8, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO MT WA		
Release destination:	CO MT WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Blanche Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Mitchell Yergert

Signature: (b) (6), (b) (7)(C)

Date: September 13, 1999

State: Colorado





United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Dr. Gary Gingery, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

September 9, 1999

Dear Dr. Gingery:

Enclosed is notification 99-251-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-251-03n	Applicant #:	99-675XRAB
Received:	September 8, 1999	Effective:	October 8, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO MT WA		
Release destination:	CO MT WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Lori M. Witham

Signature: (b) (6), (b) (7)(C)

Date: September 15, 1999

State: Montana





United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MO 20737

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

September 9, 1999

Dear Mr. Wessels:

Enclosed is notification 99-251-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-251-03n	Applicant #:	99-675XRAB
Received:	September 8, 1999	Effective:	October 8, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO MT WA		
Release destination:	CO MT WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Diane MacMeyer, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Thomas L. Wessels

Signature: (b) (6), (b) (7)(C)

Date: 9/10/99

State: WA



September 23, 1999

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C):

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3 (c), effective on or after October 8, 1999.

Interstate movement and Release
Notification no. 99-251-03n (99-675XRAB)
Regulated article - Wheat
Destinations - Colorado, Montana, Washington

You must comply with the performance standards as stated in 7 CFR 340.3 (c). In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

M. Yergert, Colorado Dept. of Agric., Lakewood, CO
R. Stoaks, PPQ, WR, Sacramento, CA
File number 99-251-03n

OR120018_BR_012640

1999 Wheat Field Test Report
USDA # 99-251-03n Monsanto # 99-675XRAB

(b) (6), (b) (7)(C)

April 16, 2001

Monsanto Company

Location

County

State

(b) (4)

Yuma
Cascade
Walla Walla

CO
MT
WA

Yuma County, CO

Planting Date: October 11, 1999

Destruct /Harvest June 2, 2000

Vector Constructs/Line Numbers Planted: (b) (4)

Purpose of Field Trial: (b) (4)

Field Monitoring for Disease Susceptibility: (b) (4)

Field Monitoring for Insect Susceptibility: (b) (4)

Field Monitoring for Plant Growth Characteristics: (b) (4)

Field Monitoring for Weediness Characteristics: (b) (4)

Method of Devitalization or Final Disposition of Plot Area after Harvesting: (b) (4)

Disposition of the seed: (b) (4)

Monitoring for Volunteer Plants: (b) (4)

Cascade County, MT

Planting Date: October 15, 1999

Destruct/ Harvest Date: Trial was destroyed on June 5, 2000.

Vector Constructs/Line Numbers Planted: (b) (4)

Purpose of Field Trial: (b) (4)

Method of Devitalization or Final Disposition of Plot Area after Harvesting: (b) (4)

Walla Walla, WA

Planting Date: October 25, 2000

Destruct/Harvest Date June 5, 2000.

Vector Constructs/Line Numbers Planted: (b) (4)

Purpose of Field Trial: (b) (4)

Field Monitoring for Disease Susceptibility: (b) (4)

Field Monitoring for Insect Susceptibility: (b) (4)

Field Monitoring for Plant Growth Characteristics: (b) (4)

Field Monitoring for Weediness Characteristics: (b) (4)

Field Monitoring for Plant Stand: (b) (4)

Method of Devitalization or Final Disposition of Plot Area after Harvesting: (b) (4)

Walla Walla, WA

Planting Date: April 4, 2000

Harvest Date: August 9, 2000

Vector Constructs/Line Numbers Planted: (b) (4)

Purpose of Field Trial: (b) (4)

Field Monitoring for Disease Susceptibility: (b) (4)

Field Monitoring for Insect Susceptibility: (b) (4)

Field Monitoring for Plant Growth Characteristics: (b) (4)

Field Monitoring for Weediness Characteristics: (b) (4)

Field Monitoring for Plant Stand: (b) (4)

Disposition of the seed: (b) (4)

9/09/99 7:56 am

Notification Tracking Sheet

=====
Bp number: 99-251-04n
=====

App number: 99-680XRAB
Received: 9/08/99
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 10/08/99
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person: (b) (6), (b) (7)(C)
Parsed name: (b) (6), (b) (7)(C)
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: (b) (6), (b) (7)(C)
Begin movement: 10/07/99
End movement: 10/06/00
Begin release: 10/07/99
End release: 10/06/00
Acre: 4.00
CBI status: CBI
Fax: 636-737-7085

=====
Initial Date
1. [✓] Assign Bp number and initial data entry [apd] [9/9/99]
2. [] Review by biotechnologist [JW]* []*
3. [✓] Letter of notification to State [BGS] [9/9/99]* fedex
4. [] State response

	O/d	Loc	Site	Reg		
Interstate	*Dest*	AZ	*	*WR	*	[] []
Interstate	*Dest*	MO	*	*SCR	*	[] []
Interstate	*Orig*	AZ	*	*WR	*	
Interstate	*Orig*	MO	*	*SCR	*	
Release	*	AZ	*	1*WR	*	[] []

5. [✓] Enter genes into database [apd] [9/9/99]
6. [✓] Letter of acknowledgement/denial/withdraw [bgs] [9/14/99]* fedex
7. [✓] Enter final data into database [bgs] [9/17/99]

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Food • Health • Hope



CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID
99-680XRAB

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 20737

Sep 07, 1999

99-251-04n

1. USDA Reference Number

2. Applicant Reference Number 99-680XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C)

FAX

636/737-7085

Monsanto Company

EMail

(b) (6), (b) (7)(C)@monsanto.com

700 Cheserfield Parkway North

St. Louis, MO

4. Duration of Introduction

Interstate Movement and Release

Oct 07, 1999 - Oct 06, 2000

5. Recipient Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: glyphosate tolerant

Cultivar/ Variety Bobwhite, BW251

CONFIDENTIAL

Monsanto Reference ID
99-680XRAB

designation of transformed line: 33391, 33456, 33463

Constructs: PV-TXGT10

genotype:

Gene of Interest

* Promoter: CMoVa/I2 -- (b) (4)

CBI

] - CBI

* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Gene of Interest

* Promoter: CMP3/I5 -- (b) (4)

CBI

- CBI

* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID
99-680XRAB

designation of transformed line: TA S1249, TA S1255, TA S1264, TA S1266, TA S1269, TA S1276,
TA S1278, TA S1364, TA S1378, TA S1455, TA S1465, TA S1472,
TA S1614, TA S1615, TA S2022, TA S2027

Constructs: PV-TXGT11

genotype:

Gene of Interest

* Promoter: CMP 3/I5 -- [(b) (4)]

- CBI

CBI

* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

* Terminator: NOS 3' +2 -- [(b) (4)]

- CBI

CBI

Gene of Interest

* Promoter: CMoVa/I5 + leader1 -- [(b) (4)]

CBI

- CBI

* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

* Terminator: M1 3' -- [(b) (4)]

CBI

CBI

CONFIDENTIAL

Monsanto Reference ID
99-680XRAB

designation of transformed line: 33512, 35710, 35845

Constructs: PV-TXGT12

genotype:

Gene of Interest

* Promoter: MP4 -- [REDACTED] (b) (4) CBI
[REDACTED]] - CBI

* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

* Terminator: M1 -- [REDACTED] (b) (4) CBI
[REDACTED] - CBI

Gene of Interest

* Promoter: CMP 3/15 -- [REDACTED] (b) (4) CBI
[REDACTED] - CBI

* Gene: CTP7-CP4 -- [REDACTED] (b) (4) CBI
[REDACTED] CBI

* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID
99-680XRAB

designation of transformed line: TA S537, TA S317, TA S342, TA S621, TA S635, TA S1081, TA S2520, TA S4490, TA S5070, TA S5450, TA S5451

Constructs: PV-TXGT13

genotype:

Gene of Interest

* Promoter: MP4 -- [(b) (4)]

CBI

] - CBI

* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

* Terminator: M1 3' -- [(b) (4)]

CBI

CBI

CONFIDENTIAL

Monsanto Reference ID
99-680XRAB

designation of transformed line: TA S2744, TA S2747

Constructs: PV-TXGT15

genotype:

Gene of Interest

- * Promoter: CMP 3/I5 -- [REDACTED] (b) (4)] - CBI *CBI*
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Gene of Interest

- * Promoter: MP4 -- [REDACTED] (b) (4) - CBI *CBI*
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: M1 3' -- [REDACTED] (b) (4) - CBI *CBI*

CONFIDENTIAL

Monsanto Reference ID
99-680XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 600 pounds of wheat seed

ORIGIN: AZ MO **DESTINATION:** AZ MO

Ship From:

AZ

* [REDACTED] (b) (4), Yuma County, AZ

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C)
Yuma County, AZ, [REDACTED] (b) (4), (b) (6), (b) (7)(C)

MO

[REDACTED] (b) (4), St. Louis County, MO (b) (4)

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C)
[REDACTED] St. Louis County, MO, [REDACTED] (b) (4), (b) (6), (b) (7)(C)

Ship To:

AZ

* [REDACTED] (b) (4) Yuma County, AZ

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C), Yuma
County, AZ, [REDACTED] (b) (4), (b) (6), (b) (7)(C)

MO

* [REDACTED] (b) (4), St. Louis County, MO (b) (4)

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C)
St. Louis County, MO, [REDACTED] (b) (4), (b) (6), (b) (7)(C) U.S.A., [REDACTED] (b) (4), (b) (6), (b) (7)(C)

Release Sites:

NUMBER OF STATES/TERRITORIES AND SITES:

CONFIDENTIAL

Monsanto Reference ID
99-680XRAB

AZ (1)

AZ

* [REDACTED] (b) (4), Yuma County, AZ up to 4 acres.

RESPONSIBLE PERSON/RESEARCHER: [REDACTED] (b) (4), (b) (6), (b) (7)(C)

[REDACTED] Yuma County, AZ. Contact: [REDACTED] (b) (4), (b) (6), (b) (7)(C)

MONSANTO

Food • Health • Hope



CONFIDENTIAL

MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

Monsanto Reference ID
99-680XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company
Sep 07, 1999

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential concerns the description of the gene introduced into corn and/or the variety into which they were transformed. The gene description category includes the names and information about genes, promoters and expressed traits.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many person years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of high solid, insect, fungal, and virus resistant crops for more than 10 years, and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the person hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this FOIA request, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the CBI Justification expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include Rhone-Poulenc, ICI, and Ciba-Geigy.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, And Expressed Traits

The release of information about the genes and promoters in the vectors will directly provide *competitors* with the knowledge of the *precise* genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the *competitors* will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity And Characteristics Of Donor Organism

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identity of Recipient Cultivars

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organism has been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification of Items claimed as Confidential Business Information

Items claimed as CBI as so indicated in the text as follows: [CBI - Deleted]. A non-confidential copy of the application is also included with the confidential item enclosed in brackets, "[]", as labeled as CBI.

MONSANTO

Food • Health • Hope



CBI - DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID
99-680XRAB

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 20737

Sep 07, 1999

99-251-04n

1. USDA Reference Number

2. Applicant Reference Number 99-680XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C)

FAX

636/737-7085

Monsanto Company

EMail

(b) (6), (b) (7)(C)@monsanto.com

700 Cheserfield Parkway North

St. Louis, MO

4. Duration of Introduction

Interstate Movement and Release

Oct 07, 1999 - Oct 06, 2000

5. Recipient Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: glyphosate tolerant

Cultivar/ Variety Bobwhite, BW251

CBI - DELETED

Monsanto Reference ID
99-680XRAB

designation of transformed line: 33391, 33456, 33463

Constructs: PV-TXGT10

genotype:

Gene of Interest

- * Promoter: CMoVa/I2 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Gene of Interest

- * Promoter: CMP3/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI - DELETED

Monsanto Reference ID
99-680XRAB

designation of transformed line: TA S1249, TA S1255, TA S1264, TA S1266, TA S1269, TA S1276, TA S1278, TA S1364, TA S1378, TA S1455, TA S1465, TA S1472, TA S1614, TA S1615, TA S2022, TA S2027

Constructs: PV-TXGT11

genotype:

Gene of Interest

- * Promoter: CMP 3/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: NOS 3' +2 -- [CBI Deleted]

Gene of Interest

- * Promoter: CMoVa/I5 + leader1 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: M1 3' -- [CBI Deleted]

CBI - DELETED

Monsanto Reference ID
99-680XRAB

designation of transformed line: 33512, 35710, 35845

Constructs: PV-TXGT12

genotype:

Gene of Interest

- * Promoter: MP4 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: M1 -- [CBI Deleted]

Gene of Interest

- * Promoter: CMP 3/I5 -- [CBI Deleted]
- * Gene: CTP7-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI - DELETED

Monsanto Reference ID
99-680XRAB

designation of transformed line: TA S537, TA S317, TA S342, TA S621, TA S635, TA S1081, TA S2520, TA S4490, TA S5070, TA S5450, TA S5451

Constructs: PV-TXGT13

genotype:

Gene of Interest

- * Promoter: MP4 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: M1 3' -- [CBI Deleted]

CBI - DELETED

Monsanto Reference ID
99-680XRAB

designation of transformed line: TA S2744, TA S2747

Constructs: PV-TXGT15

genotype:

Gene of Interest

- * Promoter: CMP 3/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Gene of Interest

- * Promoter: MP4 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: M1 3' -- [CBI Deleted]

CBI - DELETED

Monsanto Reference ID
99-680XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 600 pounds of wheat seed

ORIGIN: AZ MO **DESTINATION:** AZ MO

Ship From:

AZ

* (b) (4) Yuma County, AZ

CONTACT: (b) (6), (b) (7)(C), (b) (4)
Yuma County, AZ, (b) (4), (b) (6), (b) (7)(C)

MO

*1 (b) (4) St. Louis, St. Louis County, MO (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4)
(b) (6), (b) (7)(C), (b) (4), (b) (6), (b) (7)(C), (b) (4)

Ship To:

AZ

* (b) (4) Yuma County, AZ

CONTACT: (b) (6), (b) (7)(C), (b) (4), Yuma
County, AZ, (b) (6), (b) (7)(C), (b) (4)

MO

* (b) (4) St. Louis County, MO (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4)
St. Louis County, MO, (b) (6), (b) (7)(C), U.S.A., (b) (6), (b) (7)(C), (b) (4)

Release Sites:

NUMBER OF STATES/TERRITORIES AND SITES:

CBI - DELETED

Monsanto Reference ID
99-680XRAB

AZ (1)

AZ

*

(b) (4)

Yuma County, AZ up to 4 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4) Yuma County, AZ. Contact: (b) (6), (b) (7)(C), (b) (4)

MONSANTO

Food • Health • Hope



CBI - DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID
99-680XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

Sep 07, 1999

MONSANTO

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CBI - DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID
99-680XRAB

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 20737

Sep 07, 1999

99-251-04n

1. USDA Reference Number

2. Applicant Reference Number 99-680XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C)

FAX

636/737-7085

Monsanto Company

Email

(b) (6), (b) (7)(C)@monsanto.com

700 Cheserfield Parkway North

St. Louis, MO

4. Duration of Introduction

Interstate Movement and Release

Oct 07, 1999 - Oct 06, 2000

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: glyphosate tolerant

Cultivar/ Variety Bobwhite, BW251

Monsanto Reference ID
99-680XRAB

designation of transformed line: 33391, 33456, 33463

Constructs: PV-TXGT10

genotype:

Gene of Interest

- * Promoter: CMoVa/I2 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Gene of Interest

- * Promoter: CMP3/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI - DELETED

Monsanto Reference ID
99-680XRAB

designation of transformed line:

TA S1249, TA S1255, TA S1264, TA S1266, TA S1269, TA S1276, T,
S1278, TA S1364, TA S1378, TA S1455, TA S1465, TA S1472, TA
S1614, TA S1615, TA S2022, TA S2027

Constructs: PV-TXGT11

genotype:

Gene of Interest

- * Promoter: CMP 3/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: NOS 3' +2 -- [CBI Deleted]

Gene of Interest

- * Promoter: CMoVa/I5 + leader1 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: M1 3' -- [CBI Deleted]

Monsanto Reference ID
99-680XRAB

designation of transformed line: 33512, 35710, 35845

Constructs: PV-TXGT12

genotype:

Gene of Interest

- * Promoter: MP4 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: M1 -- [CBI Deleted]

Gene of Interest

- * Promoter: CMP 3/I5 -- [CBI Deleted]
- * Gene: CTP7-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI - DELETED

Monsanto Reference ID
99-680XRAB

designation of transformed line: TA S537, TA S317, TA S342, TA S621, TA S635, TA S1081, TA S2520, TA S4490, TA S5070, TA S5450, TA S5451

Constructs: PV-TXGT13
genotype:

Gene of Interest

- * Promoter: MP4 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: M1 3' -- [CBI Deleted]

Monsanto Reference ID
99-680XRAB

designation of transformed line: TA S2744, TA S2747

Constructs: PV-TXGT15

genotype:

Gene of Interest

- * Promoter: CMP 3/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Gene of Interest

- * Promoter: MP4 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: M1 3' -- [CBI Deleted]

CBI - DELETED

Monsanto Reference ID
99-680XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 600 pounds of wheat seed

ORIGIN:
AZ

MO

DESTINATION:
AZ

MO

Ship From:

AZ

(b) (4)

Yuma County, AZ

CONTACT: (b) (6), (b) (7)(C)
Yuma County, AZ, (b) (6), (b) (7)(C)

MO

(b) (4)

St. Louis County, MO (b) (4)

CONTACT: (b) (6), (b) (7)(C)
(b) (6), (b) (7)(C), St. Louis County, MO, (b) (6), (b) (7)(C)

Ship To:

AZ

(b) (4)

Yuma County, AZ

CONTACT: (b) (6), (b) (7)(C), Yuma
County, AZ, (b) (6), (b) (7)(C)

MO

(b) (4)

St. Louis County, MO (b) (4)

CONTACT: (b) (6), (b) (7)(C)
St. Louis County, MO, (b) (6), (b) (7)(C) U.S.A., (b) (6), (b) (7)(C)

Release Sites:

NUMBER OF STATES/TERRITORIES AND SITES:

Page 7 of 9

OR120018_BR_012672

CBI - DELETED

Monsanto Reference ID
99-680XRAB

AZ (1)

AZ

*

(b) (4)

, Yuma County, AZ up to 4 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (6), (b) (7)(C)

Yuma County, AZ. Contact: (b) (6), (b) (7)(C)

MONSANTO

Food • Health • Hope



CBI - DELETED

MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

Monsanto Reference ID
99-680XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

Sep 07, 1999

file copy

Mr. G. John Caravetta, Associate Director
Arizona Department of Agriculture
1688 W. Adams
Phoenix, AZ 85007

September 9, 1999

Dear Mr. Caravetta:

Enclosed is notification 99-251-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-251-04n	Applicant #:	99-680XRAB
Received:	September 8, 1999	Effective:	October 8, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ MO		
Release destination:	AZ		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012675

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

September 9, 1999

Dear Mr. Brown:

Enclosed is notification 99-251-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-251-04n	Applicant #:	99-680XRAB
Received:	September 8, 1999	Effective:	October 8, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ MO		
Release destination:	AZ		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012676



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. G. John Caravetta, Associate Director
Arizona Department of Agriculture
1688 W. Adams
Phoenix, AZ 85007

September 9, 1999

Dear Mr. Caravetta:

Enclosed is notification 99-251-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-251-04n	Applicant #:	99-680XRAB
Received:	September 8, 1999	Effective:	October 8, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ MO		
Release destination:	AZ		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

B. Diagne-Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

 X State concurs with APHIS determination.

 State DOES NOT CONCUR and offers the following reasons:

Name of State official: G. John Caravetta

Signature (b) (6), (b) (7)(C)

Date: 09/14/99

State: Arizona





United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

September 9, 1999

Dear Mr. Brown:

Enclosed is notification 99-251-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-251-04n	Applicant #:	99-680XRAB
Received:	September 8, 1999	Effective:	October 8, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ MO		
Release destination:	AZ		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

B. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

Y

State concurs with APHIS determination.

____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: (b) (6), (b) (7)(C)

Date: 9-13-99

State: MO



✓

September 16, 1999

(b) (6), (b) (7)(C) [REDACTED]
Monsanto Company
700 Chesterfield Parkway N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C) [REDACTED]:

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3 (c), effective on or after October 8, 1999.

Interstate movement and release
Notification no. 99-251-04n (99-680XRAB)
Regulated article - Wheat
Destination(s) - Arizona, Missouri

You must comply with the performance standards as stated in 7 CFR 340.3 (c). In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Official(s), and the Regional Program Manager(s), (Biotechnology).

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

G. Caravetta, Arizona Dept. of Agric., Phoenix, AZ
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
D. DeWeese, PPQ, SCR, Jefferson City, MO
R. Stoaks, PPQ, WR, Sacramento, CA
File number 99-251-04n

OR120018_BR_012679

1999 Wheat Field Test Report
USDA # 99-251-04n Monsanto # 99-680XRAB

(b) (6), (b) (7)(C)

April 16, 2001

Monsanto Company

Location

(b) (4)

County

Yuma

State

AZ

Yuma, AZ

Planting Date: November 2, 1999

Harvest /Destruct Date: April 20, 2000

Vector Constructs/Line Numbers Planted (b) (4)

Purpose of Field Trial: (b) (4)

Field Monitoring for Disease Susceptibility: (b) (4)

0.

Field Monitoring for Insect Susceptibility: (b) (4)

Field Monitoring for Plant Growth Characteristics: (b) (4)

Field Monitoring for Weediness Characteristics: (b) (4)

Disposition of the seed: (b) (4)

1999 Wheat Field Test Report
USDA # 99-251-04n Monsanto # 99-680XRAB
(b) (4), (b) (6), (b) (7)(C)
October 3, 2000

Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>
(b) (4)	Yuma	AZ

Yuma, AZ

Planting Date: November 2, 1999

Harvest Date: April 20, 2000

Vector Constructs/Line Numbers Planted: (b) (4)

Purpose of Field Trial: (b) (4)

Field Monitoring for Disease Susceptibility: (b) (4)

Field Monitoring for Insect Susceptibility: (b) (4)

Field Monitoring for Plant Growth Characteristics: (b) (4)

Field Monitoring for Weediness Characteristics: (b) (4)

Disposition of the seed: (b) (4)

9/09/99 7:56 am

Notification Tracking Sheet

=====
Bp number: 99-251-05n
=====

App number: 99-681XRAB Begin movement: 10/07/99
Received: 9/08/99 End movement: 10/06/00
Institution: Monsanto Begin release: 10/07/99
Recipient: Wheat End release: 10/06/00
Status: Pending Acre: 2.00
Effective date: 10/08/99 CBI status: CBI
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person: (b) (6), (b) (7)(C)
Parsed name: (b) (6), (b) (7)(C)
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: (b) (6), (b) (7)(C) Fax: 636-737-7085
=====

- | | Initial | Date |
|--|----------------|--------------------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [<i>apl</i>] | [9/9/99] |
| 2. <input type="checkbox"/> Review by biotechnologist | [<i>gn</i>]* | []* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State | [<i>BGS</i>] | [9/9/99]* <i>fedex</i> |
| 4. <input type="checkbox"/> State response | | |

	O/d	Loc	Site	Reg		
Interstate	*Dest*	AZ	*	*WR	*	[] []
Interstate	*Dest*	MO	*	*SCR	*	[] []
Interstate	*Orig*	AZ	*	*WR	*	
Interstate	*Orig*	MO	*	*SCR	*	
Release	*	AZ	*	1*WR	*	[] []

- | | | |
|--|----------------|---------------------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [<i>apl</i>] | [9/9/99] |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw | [<i>bgs</i>] | [9/16/99]* <i>fed x</i> |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [<i>bgs</i>] | [9/17/99] |

MONSANTO

Food • Health • Hope



CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID
99-681XRAB

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 20737

Sep 07, 1999

99-251-05n

1. USDA Reference Number

2. Applicant Reference Number

99-681XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company
700 Cheserfield Parkway North
St. Louis, MO

4. Duration of Introduction

Interstate Movement and Release

Oct 07, 1999 - Oct 06, 2000

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

glycosate tolerant

Cultivar/Variety Bobwhite, BW251, ACBarrie

CONFIDENTIAL

Monsanto Reference ID
99-681XRAB

designation of transformed line: 25397

Constructs: PV-TXGT05

genotype:

Gene of Interest

* Promoter: CMP3/I5 -- [(b) (4)] - CBI

CBI

* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Gene of Interest

* Promoter: CMoVa/I5 -- [(b) (4)] - CBI

CBI

* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID
99-681XRAB

AZ (1)

AZ

* [REDACTED] (b) (4) Yuma County, AZ up to 2 acres.

RESPONSIBLE PERSON/RESEARCHER: [REDACTED] (b) (4), (b) (6), (b) (7)(C)

[REDACTED], Yuma County, AZ. Contact: [REDACTED] (b) (4), (b) (6), (b) (7)(C)

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Monsanto Reference ID
99-681XRAB

MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company
Sep 07, 1999

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential concerns the description of the gene introduced into corn and/or the variety into which they were transformed. The gene description category includes the names and information about genes, promoters and expressed traits.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many person years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of high solid, insect, fungal, and virus resistant crops for more than 10 years, and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the person hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this FOIA request, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the CBI Justification expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include Rhone-Poulenc, ICI, and Ciba-Geigy.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, And Expressed Traits

The release of information about the genes and promoters in the vectors will directly provide *competitors* with the knowledge of the *precise* genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the *competitors* will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity And Characteristics Of Donor Organism

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identity of Recipient Cultivars

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organism has been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification of Items claimed as Confidential Business Information

Items claimed as CBI as so indicated in the text as follows: [CBI - Deleted]. A non-confidential copy of the application is also included with the confidential item enclosed in brackets, "[]", as labeled as CBI.

MONSANTO

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CBI - DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

http://www.monsanto.com

Monsanto Reference ID
99-681XRAB

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 20737

Sep 07, 1999

99-251-05n

1. USDA Reference Number

2. Applicant Reference Number 99-681XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C)

FAX

636/737-7085

Monsanto Company

EMail

(b) (6), (b) (7)(C)@monsanto.com

700 Cheserfield Parkway North

St. Louis, MO

4. Duration of Introduction

Interstate Movement and Release

Oct 07, 1999 - Oct 06, 2000

5. Recipient Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: glycosate tolerant

Cultivar/Variety Bobwhite, BW251, ACBarrie

CBI - DELETED

Monsanto Reference ID
99-681XRAB

designation of transformed line: 25397

Constructs: PV-TXGT05

genotype:

Gene of Interest

- * Promoter: CMP3/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Gene of Interest

- * Promoter: CMoVa/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI - DELETED

Monsanto Reference ID
99-681XRAB

7. **Mode of Transformation** Particle Bombardment
8. **Introduction** Interstate Movement and Release

Ship up to 1050 pounds of wheat seed before and after harvest

ORIGIN: AZ MO **DESTINATION:** AZ MO

Ship From:

AZ

* (b) (4), Yuma County, AZ

CONTACT: (b) (6), (b) (7)(C), (b) (4), Yuma,
Yuma County, AZ, (b) (6), (b) (7)(C), (b) (4)

MO

*] (b) (4), St. Louis County, MO (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4)
(b) (6), (b) (7)(C), (b) (4) St. Louis County, MO, (b) (6), (b) (7)(C), (b) (4)

Ship To:

AZ

* (b) (4) Yuma County, AZ

CONTACT: (b) (6), (b) (7)(C), (b) (4), Yuma
County, AZ, (b) (6), (b) (7)(C), (b) (4)

MO

* (b) (4), MO (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4),
St. Louis County, MO, (b) (6), (b) (7)(C), (b) (4)

Release Sites:

NUMBER OF STATES/TERRITORIES AND SITES:

CBI - DELETED

Monsanto Reference ID
99-681XRAB

AZ (1)

AZ

*

(b) (4)

, Yuma County, AZ up to 2 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (6), (b) (7)(C), (b) (4)
(b) (6), (b) (7)(C), (b) (4) Yuma County, AZ. Contact: (b) (6), (b) (7)(C), (b) (4)

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CBI - DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID
99-681XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

Sep 07, 1999

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CBI - DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

99-681XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 20737

Sep 07, 1999

99-251-05n

1. USDA Reference Number

2. Applicant Reference Number

99-681XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C)

FAX

636/737-7085

Monsanto Company

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

700 Cheserfield Parkway North

St. Louis, MO

4. Duration of Introduction

Interstate Movement and Release · Oct 07, 1999 - Oct 06, 2000

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

glycosate tolerant

Cultivar/Variety Bobwhite, BW251, ACBarrie

Monsanto Reference ID
99-681XRAB

designation of transformed line: 25397

Constructs: PV-TXGT05

genotype:

Gene of Interest

- * Promoter: CMP3/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Gene of Interest

- * Promoter: CMoVa/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI - DELETED

Monsanto Reference ID
99-681XRAB

7. Mode of Transformation Particle Bombardment

8. Introduction Interstate Movement and Release

Ship up to 1050 pounds of wheat seed before and after harvest

ORIGIN: AZ MO DESTINATION: AZ MO

Ship From:

AZ

* (b) (4) Yuma County, AZ

CONTACT: (b) (6), (b) (7)(C), (b) (4)
Yuma County, AZ, (b) (6), (b) (7)(C), (b) (4)

MO

* (b) (4) St. Louis County, MO (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4)
(b) (6), (b) (7)(C), (b) (4) St. Louis County, MO, (b) (6), (b) (7)(C), (b) (4)

Ship To:

AZ

* (b) (4) Yuma County, AZ

CONTACT: (b) (6), (b) (7)(C), (b) (4) Yuma
County, AZ, (b) (6), (b) (7)(C), (b) (4)

MO

* (b) (4) St. Louis County, MO (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4)
St. Louis County, MO, (b) (6), (b) (7)(C), (b) (4) U.S.A., (b) (6), (b) (7)(C), (b) (4)

Release Sites:

NUMBER OF STATES/TERRITORIES AND SITES:

Page 3 of 5

OR120018_BR_012698

CBI - DELETED

Monsanto Reference ID
99-681XRAB

AZ (1)

AZ

*

(b) (4)

Yuma County, AZ up to 2 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (6), (b) (7)(C), (b) (4)

Yuma County, AZ. Contact: (b) (6), (b) (7)(C), (b) (4)

MONSANTO

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CBI - DELETED

MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

Monsanto Reference ID
99-681XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

Sep 07, 1999

file copy

Mr. G. John Caravetta, Associate Director
Arizona Department of Agriculture
1688 W. Adams
Phoenix, AZ 85007

September 9, 1999

Dear Mr. Caravetta:

Enclosed is notification 99-251-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-251-05n	Applicant #:	99-681XRAB
Received:	September 8, 1999	Effective:	October 8, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ MO		
Release destination:	AZ		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012701

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

September 9, 1999

Dear Mr. Brown:

Enclosed is notification 99-251-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-251-05n	Applicant #:	99-681XRAB
Received:	September 8, 1999	Effective:	October 8, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ MO		
Release destination:	AZ		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012702



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. G. John Caravetta, Associate Director
Arizona Department of Agriculture
1688 W. Adams
Phoenix, AZ 85007

September 9, 1999

Dear Mr. Caravetta:

Enclosed is notification 99-251-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-251-05n	Applicant #:	99-681XRAB
Received:	September 8, 1999	Effective:	October 8, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ MO		
Release destination:	AZ		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Diana Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: G. John Caravetta

Signature: (b) (6), (b) (7)(C)

Date: 09/14/99

State: Arizona





United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

September 9, 1999

Dear Mr. Brown:

Enclosed is notification 99-251-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-251-05n	Applicant #:	99-681XRAB
Received:	September 8, 1999	Effective:	October 8, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ MO		
Release destination:	AZ		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Diane Hathmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: (b) (6), (b) (7)(C)

Date: 9-13-99

State: MO



September 16, 1999

(b) (6), (b) (7)(C) [redacted]
Monsanto Company
700 Chesterfield Parkway N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C) [redacted]:

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3 (c), effective on or after October 8, 1999.

Interstate movement and release
Notification no. 99-251-05n (99-681XRAB)
Regulated article - Wheat
Destination(s) - Arizona, Missouri

You must comply with the performance standards as stated in 7 CFR 340.3 (c). In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Official(s), and the Regional Program Manager(s), (Biotechnology).

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:
G. Caravetta, Arizona Dept. of Agric., Phoenix, AZ
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
D. DeWeese, PPQ, SCR, Jefferson City, MO
R. Stoaks, PPQ, WR, Sacramento, CA
File number 99-251-05n

OR120018_BR_012705

1999 Wheat Field Test Report
USDA # 99-251-05n Monsanto # 99-681XRAB

(b) (6), (b) (7)(C)

April 16, 2001

Monsanto Company

Location

(b) (4)

County

Yuma

State

AZ (NOT PLANTED)

9/17/99 2:44 pm

Notification Tracking Sheet

=====
Bp number: 99-259-03n
=====

App number: 99-713XRAB
Received: 9/16/99
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 10/16/99
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person: (b) (6), (b) (7)(C)
Parsed name: (b) (6), (b) (7)(C) (b) (6), (b) (7)(C)
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: 636-737-6032
Begin movement: 10/14/99
End movement: 10/13/00
Begin release: 10/14/99
End release: 10/13/00
Acre: 1.00
CBI status: CBI
Fax: 636-737-7085
=====

- | | Initial | Date |
|--|-----------|---------------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [ajd] | [9/17/99] |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist | [KZH] * | [9/20/99] * |
| 3. <input checked="" type="checkbox"/> Letter of notification to State | [BGS] | [9/21/99] * fadef |
| 4. <input type="checkbox"/> State response | | |

	O/d	Loc	Site	Reg
Interstate	*Dest*	AZ	*	*WR *
Interstate	*Dest*	MO	*	*SCR *
Interstate	*Orig*	AZ	*	*WR *
Interstate	*Orig*	MO	*	*SCR *
Release	*	AZ	*	1*WR *

- | | | |
|--|---------|----------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [ajd] | [9/20/99] |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw | [KZH] | [10/12/99] * |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [KZH] | [10/13/99] |

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MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

Monsanto Reference ID
99-713XRAB

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 20737

Sep 14, 1999

99-259-03n

1. USDA Reference Number

2. Applicant Reference Number 99-713XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C)

FAX

636/737-7085

Monsanto Company

EMail

(b) (6), (b) (7)(C)@monsanto.com

700 Cheserfield Parkway North

St. Louis, MO

4. Duration of Introduction

Interstate Movement and Release

Oct 14, 1999 - Oct 13, 2000

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: glyphosate tolerant

Cultivar/Variety Backcross progeny derived from trangenic Bobwhite and BZ991-408HW, BZ992-588, Express, Impervo, West Bred 926, West Bred 936, Brooks

CONFIDENTIAL

Monsanto Reference ID
99-713XRAB

designation of transformed line: 25397

Constructs: PV-TXGT05

genotype:

Gene of Interest

* Promoter: CMP3/I5 -- [(b) (4)] - CBI

CBI

* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Gene of Interest

* Promoter: CMoVa/I5 -- [(b) (4)] - CBI

CBI

* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID
99-713XRAB

AZ (1)

AZ

* [REDACTED] (b) (4), Yuma County, AZ 1 acres.

RESPONSIBLE PERSON/RESEARCHER: [REDACTED] (b) (4), (b) (6), (b) (7)(C)

[REDACTED] Yuma County, AZ. Contact: [REDACTED] (b) (4), (b) (6), (b) (7)(C)

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MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

Monsanto Reference ID
99-713XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company
Sep 14, 1999

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential concerns the description of the gene introduced into corn and/or the variety into which they were transformed. The gene description category includes the names and information about genes, promoters and expressed traits.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many person years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of high solid, insect, fungal, and virus resistant crops for more than 10 years, and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the person hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this FOIA request, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the CBI Justification expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include Rhone-Poulenc, ICI, and Ciba-Geigy.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, And Expressed Traits

The release of information about the genes and promoters in the vectors will directly provide *competitors* with the knowledge of the *precise* genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the *competitors* will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity And Characteristics Of Donor Organism

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identity of Recipient Cultivars

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organism has been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification of Items claimed as Confidential Business Information

Items claimed as CBI as so indicated in the text as follows: [CBI - Deleted]. A non-confidential copy of the application is also included with the confidential item enclosed in brackets, "[]", as labeled as CBI.

MONSANTO

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CBI - DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63108

PHONE (314) 694-1000

http://www.monsanto.com

Monsanto Reference ID
99-713XRAB

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 20737

Sep 14, 1999

99-259-03n

1. USDA Reference Number

2. Applicant Reference Number 99-713XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C)

FAX

636/737-7085

Monsanto Company

EMail

(b) (6), (b) (7)(C)@monsanto.com

700 Cheserfield Parkway North

St. Louis, MO

4. Duration of Introduction

Interstate Movement and Release

Oct 14, 1999 - Oct 13, 2000

5. Recipient Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: glyphosate tolerant

Cultivar/Variety Backcross progeny derived from transgenic Bobwhite and BZ991-408HW, BZ992-588, Express, Impervo, West Bred 926, West Bred 936, Brooks

CBI - DELETED

Monsanto Reference ID
99-713XRAB

designation of transformed line: 25397

Constructs: PV-TXGT05

genotype:

Gene of Interest

- * Promoter: CMP3/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Gene of Interest

- * Promoter: CMoVa/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI - DELETED

Monsanto Reference ID
99-713XRAB

7. Mode of Transformation Particle Bombardment

8. Introduction Interstate Movement and Release

Ship up to 60 pounds of wheat seed before and after harvest

ORIGIN: DESTINATION:
AZ MO AZ MO

Ship From:

AZ

* (b) (4) Yuma County, AZ (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4)
Yuma County, AZ, (b) (6), (b) (7)(C)

MO

*] (b) (4) St. Louis County, MO 63198

CONTACT: (b) (6), (b) (7)(C), (b) (4)
(b) (6), (b) (7)(C), (b) (4) St. Louis County, MO,

Ship To:

AZ

*] (b) (4) Yuma County, AZ 85366

CONTACT: (b) (6), (b) (7)(C), (b) (4)
Yuma County, AZ, (b) (6), (b) (7)(C)

MO

* (b) (4) St. Louis County, MO (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4)
(b) (6), (b) (7)(C), (b) (4) St. Louis County, MO,

Release Sites:

NUMBER OF STATES/TERRITORIES AND SITES:

CBI - DELETED

Monsanto Reference ID
99-713XRAB

AZ (1)

AZ

* (b) (4) Yuma County, AZ 1 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (6), (b) (7)(C), (b) (4)
(b) (6), (b) (7)(C), (b) (4) Yuma County, AZ. Contact: (b) (6), (b) (7)(C), (b) (4)

MONSANTO

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CBI - DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID
99-713XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

Sep 14, 1999

MONSANTO

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CBI - DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

http://www.monsanto.com

Monsanto Reference ID

99-713XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 20737

Sep 14, 1999

99-259-03n

1. USDA Reference Number

2. Applicant Reference Number

99-713XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C)

FAX

636/737-7085

Monsanto Company

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

700 Cheserfield Parkway North

St. Louis, MO

4. Duration of Introduction

Interstate Movement and Release

Oct 14, 1999 - Oct 13, 2000

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

glyphosate tolerant

Cultivar/Variety Backcross progeny derived from transgenic Bobwhite and BZ991-408HW, BZ992-588, Express, Impervo, West Bred 926, West Bred 936, Brooks

Monsanto Reference ID
99-713XRAB

designation of transformed line: 25397

Constructs: PV-TXGT05

genotype:

Gene of Interest

- * Promoter: CMP3/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.
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Gene of Interest

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CBI - DELETED

Monsanto Reference ID
99-713XRAB

7. Mode of Transformation Particle Bombardment
8. Introduction Interstate Movement and Release

Ship up to 60 pounds of wheat seed before and after harvest

ORIGIN: AZ MO DESTINATION: AZ MO

Ship From:

AZ

* (b) (4) Yuma County, AZ (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4)
Yuma County, AZ, (b) (6), (b) (7)(C)

MO

* (b) (4) ,St. Louis County, MO (b) (4)

CONTACT: (b) (6)
(b) (6), (b) (7)(C), (b) (4)

Ship To:

AZ

* (b) (4) ,Yuma County, AZ (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4)
Yuma County, AZ, (b) (6), (b) (7)(C)

MO

* REDACTED ,St. Louis County, MO (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4)
(b) (6), (b) (7)(C), (b) (4)

Release Sites:

NUMBER OF STATES/TERRITORIES AND SITES:

CBI - DELETED

Monsanto Reference ID
99-713XRAB

AZ (1)

AZ

* (b) (4), Yuma County, AZ 1 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (6), (b) (7)(C), (b) (4)
(b) (6), (b) (7)(C), (b) (4) Yuma County, AZ. Contact: (b) (6), (b) (7)(C), (b) (4)

MONSANTO

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CBI - DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID
99-713XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

Sep 14, 1999

file copy

Mr. G. John Caravetta, Associate Director
Arizona Department of Agriculture
1688 W. Adams
Phoenix, AZ 85007

September 17, 1999

Dear Mr. Caravetta:

Enclosed is notification 99-259-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-259-03n	Applicant #:	99-713XRAB
Received:	September 16, 1999	Effective:	October 16, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ MO		
Release destination:	AZ		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012726

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

September 17, 1999

Dear Mr. Brown:

Enclosed is notification 99-259-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-259-03n	Applicant #:	99-713XRAB
Received:	September 16, 1999	Effective:	October 16, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ MO		
Release destination:	AZ		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012727



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

FAXED

Mr. G. John Caravetta, Associate Director
Arizona Department of Agriculture
1688 W. Adams
Phoenix, AZ 85007

September 17, 1999

Dear Mr. Caravetta:

Enclosed is notification 99-259-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-259-03n	Applicant #:	99-713XRAB
Received:	September 16, 1999	Effective:	October 16, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ MO		
Release destination:	AZ		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: G. John Caravetta

Signature

(b) (6), (b) (7)(C)

Date: 09/22/99

State: Arizona



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An Equal Opportunity Employer

OR120018_BR_012728



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

September 17, 1999

Dear Mr. Brown:

Enclosed is notification 99-259-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-259-03n	Applicant #:	99-713XRAB
Received:	September 16, 1999	Effective:	October 16, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ MO		
Release destination:	AZ		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination.

____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: (b) (6), (b) (7)(C)

Date: 9-22-99

State: MO



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An Equal Opportunity Employer

OR120018_BR_012729

October 12, 1999

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C):

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3 (c), effective on or after October 16, 1999.

Interstate movement and Release
Notification no. 99-259-03n (99-713XRAB)
Regulated article - Wheat
Destinations - Arizona, Missouri

You must comply with the performance standards as stated in 7 CFR 340.3 (c). In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

J. Caravetta, Arizona Dept. of Agric., Phoenix, AZ
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
D. DeWeese, PPQ, SCR, Jefferson City, MO
R. Stoaks, PPQ, WR, Sacramento, CA
File number 99-259-03n

OR120018_BR_012730

99-259-03N

Reviewed
by Dr. Karen
Hobanson



ANIMAL AND PLANT HEALTH INSPECTION SERVICE

USDA APHIS PPQ

Inspection Station

Honolulu International Airport

300 Rodgers Blvd. #57

Honolulu, HI 96819-1897

FACSIMILE SHEET

TO RALPH STOAKS		OFFICE USDA APHIS PPQ	CITY AND STATE SACRAMENTO CA
OFFICE TELEPHONE NO 916-857-6105	FAX TELEPHONE NO 916-857-6156	DATE SEPT 10 1999	TIME

SUBJECT

RE. YOUR AUG 25 MEMO "PRIORITY BIOTECH INSPECTIONS"

REMARKS

RALPH:

As requested in your memo of August 25 I attach the two requested reports regarding 99-139-02n and 98-259-03n. Carol Okada (HI State) and I visited the Waimanalo fields yesterday, accompanied by Hubert Olipares (UH). Neither Dr. Stiles nor Dr. Manshardt were able to attend; the former having to appear (from what I understand) a legislative meeting, the latter having classroom teaching duties. This was unfortunate, but because of the time constraints your memo imposed together with my having to attend Federal jury duty starting next week Tuesday (for an undetermined time period), it was felt that the visit should be done as soon as possible. I hope that the attached will provide the needed information.

Bill Hoe

- ☐ ACTION
- ☐ APPROVAL
- ☒ AS REQUESTED
- ☐ FOR COMMENT
- ☐ FOR INFORMATION

FROM William J. Hoe, PhD Area Identifier - Botany		OFFICE USDA APHIS PPQ	CITY AND STATE Honolulu, Hawaii
OFFICE TELEPHONE NO. 808-861-8494	FAX TELEPHONE NO 808-861-8500	DATE Sept 10, 1999	TIME

NUMBER OF PAGES INCLUDING TRANSMITTAL SHEET

35 (will be mailed)

APHIS FORM 100-R (MAR 90)

(LOCAL REPRODUCTION AUTHORIZED)

2, this transmission.

OR120018_BR_012731



United States
Department of
Agriculture

Animal and
Plant Health
Inspection
Service

Plant Protection
and Quarantine

USDA APHIS PPQ
Inspection Station
Honolulu International Airport
300 Rodgers Blvd. #57
Honolulu, HI 96819-1897

Subject: STOAKS MEMO DATED AUGUST 25, 1999

Date: SEPTEMBER 10, 1999

To: DR. RALPH STOAKS

ATTACHMENT SHEET TO MY FAX OF SEP. 10, TO ACCOMPANY DOCUMENTS BEING MAILED.

Materials supplied by principle investigators, neither of whom was able to accompany Carol Okada and me to the Waimanalo planting site.

I. 99-139-02n (b) (6), (b) (7)(C)

4pp total, including statement from (b) (6), (b) (7)(C) indicating that the planting had not yet occurred. We visited the site; it is a fallow field. No performance standard since no planting has yet occurred.

II. 98-259-03n (b) (6), (b) (7)(C)

24pp total. Project close to termination. Perhaps due to past problems with record keeping, etc. (b) (6), (b) (7)(C) now uses an observation sheet to be filled out at the time of each visit. These have been provided to us. Performance standard attached.

III. Memo to (b) (6), (b) (7)(C) dated September 9, from (b) (6), (b) (7)(C), indicating status of the two fields. 2 pp. For your information.

IV. Copy of article from *The New York Times* for information.

Bill Hoe
Sept 10, 1999



1706

Mr. Myron Isherwood Jr., Manager
Plant Quarantine Branch
Hawaii Department of Agriculture
701 Ilalo Street
Honolulu, HI 96813

May 25, 1999

Dear Mr. Isherwood Jr.:

Enclosed is notification 99-139-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-139-02n	Applicant #:	CA-1
Received:	May 19, 1999	Effective:	June 18, 1999
Institution:	U of Hawaii	Recipient:	
Interstate destination:			
Release destination:	HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012733

Permits Branch
Biotechnology Permits
Biotechnology, Biologics, and Environmental Protection
4700 River Road
Riverdale, MD 20737-1228
Fax: 301-734-8910

1. Reference Number: 99-139-02n
2. Applicant Reference Number: CA-1
3. Applicant/Responsible party:

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

Phone: (b) (6), (b) (7)(C), (b) (4)

Fax: (b) (6), (b) (7)(C), (b) (4)

Email: (b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4), Hawaii

Phone: (b) (6), (b) (7)(C), (b) (4)

Fax: (b) (6), (b) (7)(C), (b) (4)

Email: (b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4), Hawaii

Phone: (b) (6), (b) (7)(C), (b) (4)

Fax: (b) (6), (b) (7)(C), (b) (4)

Email: (b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4), Hawaii

Phone: (b) (6), (b) (7)(C), (b) (4)

Fax: (b) (6), (b) (7)(C), (b) (4)

Email: (b) (6), (b) (7)(C), (b) (4)

4. Duration of Introduction:

Release: July 1999 - December 2004

5. Recipient: Coffee, Coffea arabica

6. Regulated Article:

a) ACC synthase cDNA in antisense orientation:

1)	Category:	Product quality (PQ)
	Phenotype:	Reduced ethylene production
	Construct:	pKRC-ACS-A
	Promoter:	35S 5' from CaMV
Gene: ACC synthase from ripening coffee fruits as cDNA in antisense orientation		
	Terminator:	NOS 3' from Agrobacterium tumifaciens
	Selectable marker:	
	Promoter:	NOS 5' from Agrobacterium tumifaciens
	Gene:	Neomycin phosphotransferase II (NPT II)
	from E. coli TN5	
	Terminator:	NOS 3' from Agrobacterium tumifaciens

7. Mode of Transformation: Coffee plants were transformed using Agrobacterium tumifaciens

8. Introduction:

Release:

NUMBER OF STATES/TERRITORIES AND SITES: HI (1)

(b) (4), HI
(City and County of Honolulu)

9. Certification: I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

Signature: _____ Date: _____

Name Typed: (b) (6), (b) (7)(C), (b) (4) _____

Permits Branch
Biotechnology Permits
Biotechnology, Biologics, and Environmental Protection
4700 River Road
Riverdale, MD 20737-1228

FAX

TO: Hubert B. Olipares
Biological Safety Officer
956-3205

FROM: (b) (6), (b) (7)(C), (b) (4)

RE: Field trials of transgenic coffee

This is to inform you that we have not, as yet initiated planting of transgenic coffee plants in (b) (4). We anticipate the initial plantings to within the next 60 days. You will be notified at least one week prior to any plantings.

If you have any questions please feel free to contact me.

(b) (6), (b) (7)(C), (b) (4)

9/17/99 2:44 pm

Notification Tracking Sheet

=====
Bp number: 99-259-04n
=====

App number: 99-714XRAB Begin movement: 10/14/99
Received: 9/16/99 End movement: 10/13/00
Institution: Monsanto Begin release: 10/14/99
Recipient: Wheat End release: 10/13/00
Status: Pending Acre: 1.00
Effective date: 10/16/99 CBI status: CBI
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person: (b) (6), (b) (7)(C)
Parsed name: (b) (6), (b) (7)(C) (b) (6), (b) (7)(C)
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: (b) (6), (b) (7)(C) Fax: 636-737-7085
=====

	Initial	Date
1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry	[apd]	[9/17/99]
2. <input checked="" type="checkbox"/> Review by biotechnologist	[KZH] *	[9/20/99] *
3. <input checked="" type="checkbox"/> Letter of notification to State	[B65]	[9/21/99] * fed x
4. <input type="checkbox"/> State response		

	O/d	Loc	Site	Reg		
Interstate	*Dest*	AZ	*	*WR	*	[] []
Interstate	*Dest*	MO	*	*SCR	*	[] []
Interstate	*Orig*	AZ	*	*WR	*	
Interstate	*Orig*	MO	*	*SCR	*	
Release	*	AZ	*	1*WR	*	[] []

5. <input checked="" type="checkbox"/> Enter genes into database	[apd]	[9/20/99]
6. <input type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw	[KZH]	[10/12/99] *
7. <input checked="" type="checkbox"/> Enter final data into database	[KZH]	[10/13/99]

MONSANTO

Food • Health • Hope



CONFIDENTIAL

MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

Monsanto Reference ID
99-714XRAB

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 20737

Sep 14, 1999

99-259-04n

1. USDA Reference Number

2. Applicant Reference Number 99-714XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C)

FAX

636/737-7085

Monsanto Company

EMail

(b) (6), (b) (7)(C)@monsanto.com

700 Cheserfield Parkway North

St. Louis, MO

4. Duration of Introduction

Interstate Movement and Release

Oct 14, 1999 - Oct 13, 2000

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: glyphosate tolerant

Cultivar/Variety Backcrosses progeny derived from transgenic Bobwhite and BZ991-408HW, BZ992-588, Express, Impervo, West Bred 926, West Bred 936, Brooks

CONFIDENTIAL

Monsanto Reference ID
99-714XRAB

designation of transformed line: 33391, 33456, 33463

Constructs: PV-TXGT10

genotype:

Gene of Interest

* Promoter: CMoVa/I2 -- (b) (4)

CBI

] - CBI

* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Gene of Interest

* Promoter: CMP3/I5 -- (b) (4)

CBI

- CBI

* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID
99-714XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

genotype:

Gene of Interest

* Promoter: MP4 -- [(b) (4)] - CBI

* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

* Terminator: M1 -- (b) (4)] - CBI

Gene of Interest

* Promoter: CMP 3/15 -- (b) (4) - CBI

* Gene: CTP7-CP4 -- [(b) (4)] - CBI

* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID
99-714XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 60 pounds of wheat seed before and after harvest.

ORIGIN: AZ MO DESTINATION: AZ MO

Ship From:

AZ

* (b) (4), Yuma County, AZ (b) (4)

CONTACT: (b) (4), (b) (6), (b) (7)(C)
Yuma County, AZ, (b) (4), (b) (6), (b) (7)(C)

MO

(b) (4), St. Louis County, MO (b) (4)

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), St. Louis County, MO (b) (4), (b) (6), (b) (7)(C)

Ship To:

AZ

(b) (4), Yuma County, AZ (b) (4)

CONTACT: (b) (4), (b) (6), (b) (7)(C)
Yuma County, AZ, (b) (4), (b) (6), (b) (7)(C)

MO

* (b) (4), St. Louis County, MO (b) (4)

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), St. Louis County, MO (b) (4), (b) (6), (b) (7)(C)

Release Sites:

NUMBER OF STATES/TERRITORIES AND SITES:

CONFIDENTIAL

Monsanto Reference ID
99-714XRAB

AZ (1)

AZ

* [REDACTED] (b) (4) [REDACTED], Yuma County, AZ 1 acres.

RESPONSIBLE PERSON/RESEARCHER: [REDACTED] (b) (4), (b) (6), (b) (7)(C)

[REDACTED] Yuma County, AZ. Contact: [REDACTED] (b) (4), (b) (6), (b) (7)(C)

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Food • Health • Hope



CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID
99-714XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

Sep 14, 1999

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential concerns the description of the gene introduced into corn and/or the variety into which they were transformed. The gene description category includes the names and information about genes, promoters and expressed traits.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many person years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of high solid, insect, fungal, and virus resistant crops for more than 10 years, and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the person hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this FOIA request, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the CBI Justification expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include Rhone-Poulenc, ICI, and Ciba-Geigy.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, And Expressed Traits

The release of information about the genes and promoters in the vectors will directly provide *competitors* with the knowledge of the *precise* genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the *competitors* will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity And Characteristics Of Donor Organism

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identity of Recipient Cultivars

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organism has been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification of Items claimed as Confidential Business Information

Items claimed as CBI as so indicated in the text as follows: [CBI - Deleted]. A non-confidential copy of the application is also included with the confidential item enclosed in brackets, "[]", as labeled as CBI.

MONSANTO

Food • Health • Hope



CBI - DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

St. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID
99-714XRAB

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 20737

Sep 14, 1999

99-259-04n

1. USDA Reference Number

2. Applicant Reference Number 99-714XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

Monsanto Company

EMail

(b) (6), (b) (7)(C)@monsanto.com

700 Cheserfield Parkway North

St. Louis, MO

4. Duration of Introduction

Interstate Movement and Release

Oct 14, 1999 - Oct 13, 2000

5. Recipient Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: glyphosate tolerant

Cultivar/Variety Backcrosses progeny derived from transgenic Bobwhite and BZ991-408HW, BZ992-588, Express, Impervo, West Bred 926, West Bred 936, Brooks

CBI - DELETED

Monsanto Reference ID
99-714XRAB

designation of transformed line: 33391, 33456, 33463

Constructs: PV-TXGT10

genotype:

Gene of Interest

- * Promoter: CMoVa/I2 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Gene of Interest

- * Promoter: CMP3/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI - DELETED

Monsanto Reference ID
99-714XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

genotype:

Gene of Interest

- * Promoter: MP4 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: M1 -- [CBI Deleted]

Gene of Interest

- * Promoter: CMP 3/15 -- [CBI Deleted]
- * Gene: CTP7-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI - DELETED

Monsanto Reference ID
99-714XRAB

7. Mode of Transformation Disarmed *Agrobacterium tumefaciens*

8. Introduction Interstate Movement and Release

Ship up to 60 pounds of wheat seed before and after harvest.

ORIGIN: AZ MO **DESTINATION:** AZ MO

Ship From:

AZ

* (b) (4) ,Yuma County, AZ (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4)
Yuma County, AZ, 85366

MO

* (b) (4) ,St. Louis County, MO (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4)
St. Louis County, MO, (b) (6), (b) (7)(C), (b) (4)

Ship To:

AZ

* (b) (4) Yuma County, AZ (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4)
Yuma County, AZ, (b) (6), (b) (7)(C)

MO

* (b) (4) ,St. Louis County, MO (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4)
St. Louis County, MO, (b) (6), (b) (7)(C), (b) (4)

Release Sites:

NUMBER OF STATES/TERRITORIES AND SITES:

CBI - DELETED

Monsanto Reference ID
99-714XRAB

AZ (1)

AZ

* (b) (4), Yuma County, AZ 1 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (6), (b) (7)(C), (b) (4)
(b) (6), (b) (7)(C), (b) (4) Yuma County, AZ. Contact: (b) (6), (b) (7)(C), (b) (4)

MONSANTO

Food • Health • Hope



CBI - DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID
99-714XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

Sep 14, 1999

MONSANTO

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CBI - DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

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Monsanto Reference ID
99-714XRAB

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 20737

Sep 14, 1999

99-259-04n

1. USDA Reference Number

2. Applicant Reference Number 99-714XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C)

FAX

636/737-7085

Monsanto Company

EMail

(b) (6), (b) (7)(C)@monsanto.com

700 Cheserfield Parkway North

St. Louis, MO

4. Duration of Introduction

Interstate Movement and Release

Oct 14, 1999 - Oct 13, 2000

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: glyphosate tolerant

Cultivar/Variety Backcrosses progeny derived from transgenic Bobwhite and BZ991-408HW, BZ992-588, Express, Impervo, West Bred 926, West Bred 936, Brooks

Monsanto Reference ID
99-714XRAB

designation of transformed line: 33391, 33456, 33463

Constructs: PV-TXGT10

genotype:

Gene of Interest

- * Promoter: CMoVa/I2 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Gene of Interest

- * Promoter: CMP3/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI - DELETED

Monsanto Reference ID
99-714XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

genotype:

Gene of Interest

- * Promoter: MP4 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: M1 -- [CBI Deleted]

Gene of Interest

- * Promoter: CMP 3/15 -- [CBI Deleted]
- * Gene: CTP7-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI - DELETED

Monsanto Reference ID
99-714XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 60 pounds of wheat seed before and after harvest.

ORIGIN: AZ MO DESTINATION: AZ MO

Ship From:

AZ

* [REDACTED] (b) (4), Yuma County, AZ (b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)
Yuma County, AZ, (b) (6), (b) (7)(C)

MO

[REDACTED] (b) (4), St. Louis County, MO (b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)
[REDACTED] St. Louis County, MO, (b) (6), (b) (7)(C), (b) (4)

Ship To:

AZ

[REDACTED] (b) (4), Yuma County, AZ (b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)
Yuma County, AZ, (b) (6), (b) (7)(C)

MO

* [REDACTED] (b) (4), St. Louis County, MO (b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)
[REDACTED] St. Louis County, MO, (b) (6), (b) (7)(C), (b) (4)

Release Sites:

NUMBER OF STATES/TERRITORIES AND SITES:

CBI - DELETED

Monsanto Reference ID
99-714XRAB

AZ (1)

AZ

* [REDACTED] (b) (4), Yuma County, AZ 1 acres.

RESPONSIBLE PERSON/RESEARCHER: [REDACTED] (b) (6), (b) (7)(C), (b) (4)

[REDACTED] Yuma County, AZ. Contact [REDACTED] (b) (6), (b) (7)(C), (b) (4)

MONSANTO

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CBI - DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID
99-714XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (7)(C), (b) (6)

Monsanto Company

Sep 14, 1999

file copy

Mr. G. John Caravetta, Associate Director
Arizona Department of Agriculture
1688 W. Adams
Phoenix, AZ 85007

September 17, 1999

Dear Mr. Caravetta:

Enclosed is notification 99-259-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-259-04n	Applicant #:	99-714XRAB
Received:	September 16, 1999	Effective:	October 16, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ MO		
Release destination:	AZ		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012759

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

September 17, 1999

Dear Mr. Brown:

Enclosed is notification 99-259-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-259-04n	Applicant #:	99-714XRAB
Received:	September 16, 1999	Effective:	October 16, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ MO		
Release destination:	AZ		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012760



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

FILED

Mr. G. John Caravetta, Associate Director
Arizona Department of Agriculture
1688 W. Adams
Phoenix, AZ 85007

September 17, 1999

Dear Mr. Caravetta:

Enclosed is notification 99-259-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-259-04n	Applicant #:	99-714XRAB
Received:	September 16, 1999	Effective:	October 16, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ MO		
Release destination:	AZ		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (7)(C), (b) (6)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: G. John Caravetta

Signature: **(b) (7)(C), (b) (6)**

Date: 09/22/99

State: Arizona



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An Equal Opportunity Employer

OR120018_BR_012761



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

September 17, 1999

Dear Mr. Brown:

Enclosed is notification 99-259-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-259-04n	Applicant #:	99-714XRAB
Received:	September 16, 1999	Effective:	October 16, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ MO		
Release destination:	AZ		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (7)(C), (b) (6)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: _____

(b) (7)(C), (b) (6)

Date: 9-22-99

State: MO



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_012762

TOTAL P.03

October 12, 1999

(b) (7)(C), (b) (7)(D) [redacted]
Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (7)(C), (b) (7)(D) [redacted]:

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3 (c), effective on or after October 16, 1999.

Interstate movement and Release
Notification no. 99-259-04n (99-714XRAB)
Regulated article - Wheat
Destinations - Arizona, Missouri

You must comply with the performance standards as stated in 7 CFR 340.3 (c). In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

J. Caravetta, Arizona Dept. of Agric., Phoenix, AZ
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
D. DeWeese, PPQ, SCR, Jefferson City, MO
R. Stoaks, PPQ, WR, Sacramento, CA

File number 99-259-04n

OR120018_BR_012763

1999 Wheat Field Test Report
USDA # 99-259-04n Monsanto # 99-714XRAB

(b) (7)(C), (b) (6)

April 16, 2001

Monsanto Company

Location

(b) (4)

County

Yuma

State

AZ

Yuma, AZ

Planting Date: January 15, 2000

Harvest Date: May 2, 2000

Vector Constructs/Line Numbers Planted: (b) (4)

Purpose of Field Trial: (b) (4)

Field Monitoring for Disease Susceptibility: (b) (4)

Field Monitoring for Insect Susceptibility: (b) (4)

Field Monitoring for Plant Growth Characteristics: (b) (4)

Field Monitoring for Weediness Characteristics: (b) (4)

Field Monitoring for Plant Stand: (b) (4)

Disposition of the seed: (b) (4)

1999 Wheat Field Test Report
USDA # 99-259-04n Monsanto # 99-714XRAB
(b) (7)(C), (b) (6)
October 4, 2000

Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>
(b) (4)	Yuma	AZ

Yuma, AZ

Planting Date: January 15, 2000

Harvest Date: May 2, 2000

Vector Constructs/Line Numbers Planted: (b) (4)

Purpose of Field Trial: (b) (4)

Field Monitoring for Disease Susceptibility: (b) (4)

Field Monitoring for Insect Susceptibility: (b) (4)

Field Monitoring for Plant Growth Characteristics: (b) (4)

Field Monitoring for Weediness Characteristics: (b) (4)

Field Monitoring for Plant Stand: (b) (4)

Disposition of the seed: (b) (4)

9/28/99 8:56 am

Notification Tracking Sheet

=====

Bp number: 99-266-02n

=====

App number: 99-726XRAB Begin movement: 10/21/99
 Received: 9/23/99 End movement: 10/20/00
 Institution: Monsanto Begin release: 10/21/99
 Recipient: Wheat End release: 10/20/00
 Status: Pending Acre: 8.00
 Effective date: 10/23/99 CBI status: CBI
 Phenotype: HT - Glyphosate tolerant
 Comments:
 Resp person: (b) (7)(C), (b) (6)
 Parsed name: (b) (7)(C), (b) (6)
 Address1: Monsanto Company
 Address2: 700 Chesterfield Parkway N.
 Address3:
 Address4:
 City/State/Zip: Chesterfield, MO 63198
 Telephone: (b) (7)(C), (b) (6) Fax: 636-737-7085

=====

	Initial	Date
1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry	[ajd]	[9/28/99]
2. <input checked="" type="checkbox"/> Review by biotechnologist	[AMK] *	[9/29/99] *
3. <input checked="" type="checkbox"/> Letter of notification to State	[KZLO]	[9/29/99] *
4. <input type="checkbox"/> State response		

O/d	Loc	Site	Reg		
Interstate	*Dest*CA	*	*WR	*	[] []
Interstate	*Dest*HI	*	*WR	*	[] []
Interstate	*Dest*MO	*	*SCR	*	[] []
Interstate	*Orig*CA	*	*WR	*	
Interstate	*Orig*HI	*	*WR	*	
Interstate	*Orig*MO	*	*SCR	*	
Release	*CA	*	2*WR	*	[] []
Release	*HI	*	1*WR	*	[] []

5. <input type="checkbox"/> Enter genes into database	[]	[]
6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw	[KZLO]	[10/25/99] *
7. <input type="checkbox"/> Enter final data into database	[KZLO]	[10/26/99]

MONSANTO

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CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID
99-726XRAB

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 20737

Sep 21, 1999

99-266-02n

1. USDA Reference Number

2. Applicant Reference Number 99-726XRAB

3. Applicant/Responsible Party

(b) (7)(C), (b) (6)

Phone

(b) (7)(C), (b) (6)

FAX

636/737-7085

EMail

(b) (7)(C), (b) (6)@monsanto.com

Monsanto Company
700 Cheserfield Parkway North
St. Louis, MO

4. Duration of Introduction

Interstate Movement and Release Oct 21, 1999 - Oct 20, 2000

5. Recipient Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/ Variety Bobwhite, BW251, AC Barrie

CONFIDENTIAL

Monsanto Reference ID
99-726XRAB

designation of transformed line: 33391, 33456, 33463

Constructs: PV-TXGT10

genotype:

Gene of Interest

* Promoter: CMoVa/I2 -- [(b) (4)]

CBI

- CBI

* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Gene of Interest

* Promoter: CMP3/I5 -- [(b) (4)]

CBI

- CBI

* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID
99-726XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

genotype:

Gene of Interest

* Promoter: MP4 -- (b) (4) CBI
- CBI

* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

* Terminator: M1 -- (b) (4) CBI
- CBI

Gene of Interest

* Promoter: CMP 3/15 -- (b) (4) CBI
- CBI

* Gene: CTP7-CP4 -- (b) (4) CBI
- CBI

* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID
99-726XRAB

7. **Mode of Transformation** Disarmed Agrobacterium tumefaciens
8. **Introduction** Interstate Movement and Release

Ship up to 9000 pounds of wheat seed before and after harvest

ORIGIN:		DESTINATION:	
CA	HI	CA	HI
MO		MO	

Ship From:

CA

§ (b) (4), Kern County, CA (b) (4)

CONTACT: (b) (4), (b) (6), (b) (7)(C)
Kern County, CA (b) (4), (b) (6), (b) (7)(C)

§ (b) (4), Imperial County, CA

CONTACT: (b) (4), (b) (6), (b) (7)(C),
Yuma County, AZ, (b) (4), (b) (6), (b) (7)(C)

HI

§ (b) (4), Honolulu County, HI
(b) (4)

CONTACT: (b) (4), (b) (6), (b) (7)(C)
Honolulu County, HI, (b) (4), (b) (6), (b) (7)(C)

MO

§ (b) (4), St. Louis County, MO (b) (4)

CONTACT: (b) (4), (b) (6), (b) (7)(C)
St. Louis County, MO, (b) (4), (b) (6), (b) (7)(C)

Ship To:

CA

CONFIDENTIAL

Monsanto Reference ID
99-726XRAB

(b) (4), Kern County, CA (b) (4)

CONTACT: (b) (4), (b) (6), (b) (7)(C)
Kern County, CA, (b) (4), (b) (6), (b) (7)(C) USA

* (b) (4), Imperial County, CA

CONTACT: (b) (4), (b) (6), (b) (7)(C), Yuma
County, AZ, (b) (4), (b) (6), (b) (7)(C)

HI

(b) (4), Honolulu County, HI
(b) (4)

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), Honolulu County, HI, (b) (4), (b) (6), (b) (7)(C)

MO

(b) (4), St. Louis County, MO (b) (4)

CONTACT: (b) (4), (b) (6), (b) (7)(C)
St. Louis County, MO, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

Release Sites:

NUMBER OF STATES/TERRITORIES AND SITES:

CA (2) HI (1)

CA

* (b) (4), Kern County, CA 1 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4) Kern County, CA. Contact: (b) (4), (b) (6), (b) (7)(C),

* (b) (4), Imperial County, CA 2 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4) Yuma County, AZ. Contact: (b) (4), (b) (6), (b) (7)(C)

CONFIDENTIAL

Monsanto Reference ID
99-726XRAB

HI

* [REDACTED] (b) (4) Honolulu County, HI 5 acres.

RESPONSIBLE PERSON/RESEARCHER: [REDACTED] (b) (4), (b) (6), (b) (7)(C)
[REDACTED] Honolulu County, HI. Contact: [REDACTED] (b) (4), (b) (6), (b) (7)(C)

MONSANTO

Food • Health • Hope



CONFIDENTIAL

MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

Monsanto Reference ID
99-726XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company
Sep 21, 1999

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential concerns the description of the gene introduced into corn and/or the variety into which they were transformed. The gene description category includes the names and information about genes, promoters and expressed traits.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many person years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of high solid, insect, fungal, and virus resistant crops for more than 10 years, and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the person hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this FOIA request, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the CBI Justification expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include Rhone-Poulenc, ICI, and Ciba-Geigy.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, And Expressed Traits

The release of information about the genes and promoters in the vectors will directly provide *competitors* with the knowledge of the *precise* genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the *competitors* will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity And Characteristics Of Donor Organism

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identity of Recipient Cultivars

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organism has been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification of Items claimed as Confidential Business Information

Items claimed as CBI as so indicated in the text as follows: [CBI - Deleted]. A non-confidential copy of the application is also included with the confidential item enclosed in brackets, "[]", as labeled as CBI.

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CBI - DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID
99-726XRAB

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 20737

Sep 21, 1999

99-266-02n

1. USDA Reference Number

2. Applicant Reference Number 99-726XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C)

FAX

636/737-7085

Monsanto Company

EMail

(b) (6), (b) (7)(C)@monsanto.com

700 Cheserfield Parkway North

St. Louis, MO

4. Duration of Introduction

Interstate Movement and Release

Oct 21, 1999 - Oct 20, 2000

5. Recipient Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/ Variety Bobwhite, BW251, AC Barrie

CBI - DELETED

Monsanto Reference ID
99-726XRAB

designation of transformed line: 33391, 33456, 33463

Constructs: PV-TXGT10

genotype:

Gene of Interest

- * Promoter: CMoVa/I2 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Gene of Interest

- * Promoter: CMP3/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI - DELETED

Monsanto Reference ID
99-726XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

genotype:

Gene of Interest

- * Promoter: MP4 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: M1 -- [CBI Deleted]

Gene of Interest

- * Promoter: CMP 3/I5 -- [CBI Deleted]
- * Gene: CTP7-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI - DELETED

Monsanto Reference ID
99-726XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 9000 pounds of wheat seed before and after harvest

ORIGIN:

CA

HI

MO

DESTINATION:

CA

HI

MO

Ship From:

CA

(b) (4), Kern County, CA (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4), Kern County, CA, (b) (6), (b) (7)(C), (b) (4)

(b) (4) Imperial County, CA

CONTACT: (b) (6), (b) (7)(C), (b) (4)

Yuma County, AZ, (b) (6), (b) (7)(C), (b) (4)

HI

(b) (4), Honolulu County, HI
(b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4), Honolulu County, HI, (b) (6), (b) (7)(C), (b) (4)

MO

(b) (4), St. Louis County, MO (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4), St. Louis County, MO, (b) (6), (b) (7)(C), (b) (4)

Ship To:

CA

CBI - DELETED

Monsanto Reference ID
99-726XRAB

* [REDACTED] (b) (4), Kern County, CA (b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)
Kern County, CA (b) (6), (b) (7)(C), (b) (4) USA

* [REDACTED] (b) (4), Imperial County, CA

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4), Yuma
County, AZ, (b) (6), (b) (7)(C), (b) (4)

HI

* [REDACTED] (b) (4), Honolulu County, HI
(b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)
[REDACTED] Honolulu County, HI, (b) (6), (b) (7)(C), (b) (4)

MO

* [REDACTED] (b) (4), St. Louis County, MO (b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)
St. Louis County, MO, (b) (6), (b) (7)(C), (b) (4) U.S.A., (b) (6), (b) (7)(C), (b) (4)

Release Sites:

NUMBER OF STATES/TERRITORIES AND SITES:

CA (2) HI (1)

CA

* [REDACTED] (b) (4) Kern County, CA 1 acres.

RESPONSIBLE PERSON/RESEARCHER: [REDACTED] (b) (6), (b) (7)(C), (b) (4)
[REDACTED] Kern County, CA. Contact: (b) (6), (b) (7)(C), (b) (4),

* [REDACTED] (b) (4), Imperial County, CA 2 acres.

RESPONSIBLE PERSON/RESEARCHER: [REDACTED] (b) (6), (b) (7)(C), (b) (4)
[REDACTED] Yuma County, AZ. Contact: (b) (6), (b) (7)(C), (b) (4)

CBI - DELETED

Monsanto Reference ID
99-726XRAB

HI

* [REDACTED] (b) (4), Honolulu County, HI 5 acres.

RESPONSIBLE PERSON/RESEARCHER: [REDACTED] (b) (6), (b) (7)(C), (b) (4)
[REDACTED] Honolulu County, HI. Contact [REDACTED] (b) (6), (b) (7)(C), (b) (4)

MONSANTO

Food • Health • Hope



CBI - DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

St. Louis, Missouri 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID
99-726XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

Sep 21, 1999

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CBI - DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID
99-726XRAB

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 20737

Sep 21, 1999

99-266-02n

1. USDA Reference Number

2. Applicant Reference Number 99-726XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

Monsanto Company

EEmail

(b) (6), (b) (7)(C)@monsanto.com

700 Cheserfield Parkway North

St. Louis, MO

4. Duration of Introduction

Interstate Movement and Release

Oct 21, 1999 - Oct 20, 2000

5. Recipient Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/ Variety Bobwhite, BW251, AC Barrie

CBI - DELETED

Monsanto Reference ID
99-726XRAB

designation of transformed line: 33391, 33456, 33463

Constructs: PV-TXGT10

genotype:

Gene of Interest

- * Promoter: CMoVa/I2 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Gene of Interest

- * Promoter: CMP3/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI - DELETED

Monsanto Reference ID
99-726XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

genotype:

Gene of Interest

- * Promoter: MP4 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: M1 -- [CBI Deleted]

Gene of Interest

- * Promoter: CMP 3/I5 -- [CBI Deleted]
- * Gene: CTP7-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI - DELETED

Monsanto Reference ID
99-726XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 9000 pounds of wheat seed before and after harvest

ORIGIN:

CA

HI

DESTINATION:

CA

HI

MO

MO

Ship From:

CA

* [REDACTED] (b) (4), Kern County, CA (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4)

[REDACTED] Kern County, CA (b) (4), (b) (5), (b) (6)

* [REDACTED] (b) (4), Imperial County, CA

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)

Yuma County, AZ, (b) (6), (b) (7)(C), (b) (4)

HI

[REDACTED] (b) (4), Honolulu County, HI
(b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)

[REDACTED] Honolulu County, HI, (b) (6), (b) (7)(C), (b) (4)

MO

* [REDACTED] (b) (4) St. Louis County, MO (b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)

[REDACTED] St. Louis County, MO, (b) (6), (b) (7)(C), (b) (4)

Ship To:

CA

CBI - DELETED

Monsanto Reference ID
99-726XRAB

* [REDACTED] (b) (4), Kern County, CA (b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)
Kern County, CA, [REDACTED] (b) (6), (b) (7)(C), (b) (4) USA

* [REDACTED] (b) (4), Imperial County, CA

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4), Yuma
County, AZ, [REDACTED] (b) (6), (b) (7)(C), (b) (4)

HI

* [REDACTED] (b) (4), Honolulu County, HI
(b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)
[REDACTED] Honolulu County, HI, [REDACTED] (b) (6), (b) (7)(C), (b) (4)

MO

* [REDACTED] (b) (4), St. Louis County, MO (b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)
St. Louis County, MO, [REDACTED] (b) (6), (b) (7)(C), (b) (4) U.S.A., [REDACTED] (b) (6), (b) (7)(C), (b) (4)

Release Sites:

NUMBER OF STATES/TERRITORIES AND SITES:

CA (2) HI (1)

CA

* [REDACTED] (b) (4), Kern County, CA 1 acres.

RESPONSIBLE PERSON/RESEARCHER: [REDACTED] (b) (6), (b) (7)(C), (b) (4)
[REDACTED] Kern County, CA. Contact: [REDACTED] (b) (6), (b) (7)(C), (b) (4),

* [REDACTED] (b) (4), Imperial County, CA 2 acres.

RESPONSIBLE PERSON/RESEARCHER: [REDACTED] (b) (6), (b) (7)(C), (b) (4)
[REDACTED] Yuma County, AZ. Contact: [REDACTED] (b) (6), (b) (7)(C), (b) (4)

CBI - DELETED

Monsanto Reference ID
99-726XRAB

HI

* [REDACTED] (b) (4), Honolulu County, HI 5 acres.

RESPONSIBLE PERSON/RESEARCHER: [REDACTED] (b) (6), (b) (7)(C), (b) (4)
[REDACTED] Honolulu County, HI. Contact: [REDACTED] (b) (6), (b) (7)(C), (b) (4)

MONSANTO

Food • Health • Hope



CBI - DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

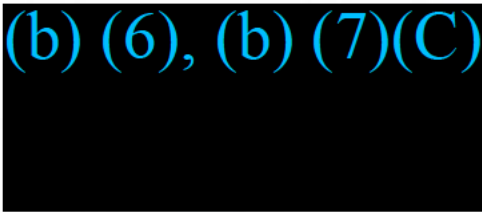
<http://www.monsanto.com>

Monsanto Reference ID
99-726XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

Sep 21, 1999

file copy

Ms. Barbara Hass, State Regulatory Official
California Department of Food and Agriculture
1220 N Street - Rm A-372
Sacramento, CA 95814

September 28, 1999

Dear Ms. Hass:

Enclosed is notification 99-266-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-266-02n	Applicant #:	99-726XRAB
Received:	September 23, 1999	Effective:	October 23, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA HI MO		
Release destination:	CA HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012791

file copy

Mr. Myron Isherwood Jr., Manager
Plant Quarantine Branch
Hawaii Department of Agriculture
701 Ilalo Street
Honolulu, HI 96813

September 28, 1999

Dear Mr. Isherwood Jr.:

Enclosed is notification 99-266-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-266-02n	Applicant #:	99-726XRAB
Received:	September 23, 1999	Effective:	October 23, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA HI MO		
Release destination:	CA HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012792

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

September 28, 1999

Dear Mr. Brown:

Enclosed is notification 99-266-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-266-02n	Applicant #:	99-726XRAB
Received:	September 23, 1999	Effective:	October 23, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA HI MO		
Release destination:	CA HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012793



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Ms. Barbara Hass, State Regulatory Official
California Department of Food and Agriculture
1220 N Street - Rm A-372
Sacramento, CA 95814

September 28, 1999

Dear Ms. Hass:

Enclosed is notification 99-266-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-266-02n	Applicant #:	99-726XRAB
Received:	September 23, 1999	Effective:	October 23, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA HI MO		
Release destination:	CA HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination provided, wheat seed from Missouri is prohibited unless it meets the requirements of Title 3, Calif. Code of Regs., Section 3277, Cereal Leaf
☐ State DOES NOT CONCUR and offers the following reasons: Beetle Exterior Quarantine.

Name of State official: Barbara J. Hass (916) 654-1017

Signature: (b) (6), (b) (7)(C)

Date: October 5, 1999

State: California



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OCT 7 1999

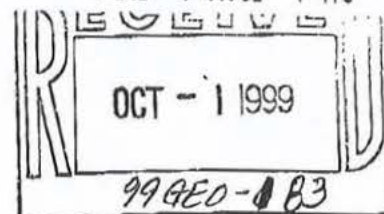
OR120018_BR_012794



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737



September 28, 1999

Mr. Myron Isherwood Jr., Manager
Plant Quarantine Branch
Hawaii Department of Agriculture
701 Ilalo Street
Honolulu, HI 96813

Dear Mr. Isherwood Jr.:

Enclosed is notification 99-266-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-266-02n	Applicant #:	99-726XRAB
Received:	September 23, 1999	Effective:	October 23, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA HI MO		
Release destination:	CA HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination. Please notify Ms. Carol Okada,
Hawaii Dept. of Agriculture, 701 Ilalo St. Honolulu, HI 96813
☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Carol L. Okada

Signature: (b) (6), (b) (7)(C)

Date: 12 October 1999

State: Hawaii



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An Equal Opportunity Employer

OCT 14 1999

OR120018_BR_012795



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

September 28, 1999

Dear Mr. Brown:

Enclosed is notification 99-266-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-266-02n	Applicant #:	99-726XRAB
Received:	September 23, 1999	Effective:	October 23, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA HI MO		
Release destination:	CA HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: 10/4/99

State: MO



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AN Equal Opportunity Employer

OR120018_BR_012796

October 25, 1999

(b) (6), (b) (7)(C)
Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C):

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3 (c), effective on or after October 25, 1999.

Interstate movement and Release
Notification no. 99-266-02n (726XRAB)
Regulated article - Wheat
Destinations - California, Hawaii, Missouri

You must comply with the performance standards as stated in 7 CFR 340.3 (c). All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

The State of California concurs with APHIS determination; provided, wheat seed from Missouri is prohibited unless it meets the requirements of Title 3, California Code of Regulations, Section 3277, Cereal Leaf Beetle Exterior Quarantine.

In addition, the State of Hawaii has requested that you adhere to the following requirements:

1. The field should remain fallow for a minimum of thirty days. During the fallow period, the field should be watered by overhead irrigation to allow the germination of volunteer wheat. Volunteer wheat should be destroyed.
2. Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 701 Ilalo Street, Honolulu, Hawaii 96813, at each of the following times:
 - a) All planting, pollinating and harvesting dates of each field trial.
 - b) Any changes to the field sites, recommended conditions, or other related matters.
 - c) The unplanned release or theft of any transgenic wheat plants or plant parts.
3. Submit a written report on the field test data including information on:

OR120018_BR_012797

- a) The germination of volunteer wheat after harvest.
- b) Pollen movement and viability under island's climatic conditions, and any occurrence of introduced traits transferred to non-test plants.

The report should be submitted to the Plant Quarantine Branch, 701 Ilalo Street, Honolulu, Hawaii, 96813, with a copy to Ms. Carol Okada, within six months of completion or termination of the test.

- 4. The introduction of any organism other than wheat seeds may be regulated by the Plant Quarantine Branch. For more information on the organisms regulated by the Branch, please contact Mr. Myron Isherwood Jr., Hawaii Department of Agriculture.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Biotechnology Evaluations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

B. Hass, California Dept. of Food and Agric., Sacramento, CA
M. Isherwood, Hawaii Dept. of Agric., Honolulu, HI
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
R. Stoaks, PPQ, WR, Sacramento, CA
D. DeWeese, PPQ, SCR, Jefferson City, MO
File number 99-266-02n

1999 Wheat Field Trial Report
USDA # 99-266-02n Monsanto # 99-726XRAB

(b) (6), (b) (7)(C)
May 8, 2001
Monsanto Company

Location	County	State
(b) (4)	Imperial	AZ (NOT PLANTED)
(b) (4)	Kern	CA
(b) (4)	Honolulu	HI

Kern County, CA

Planting Date December 8, 1999

Harvest Date: June 25, 2000

Vector Constructs/Line Numbers Planted: (b) (4)

Purpose of trial: Crosses

Field Monitoring for Disease Susceptibility: (b) (4)

Field Monitoring for Insect Susceptibility: (b) (4)

Field Monitoring for Plant Growth Characteristics: (b) (4)

Field Monitoring for Weediness Characteristics: (b) (4)

Field Monitoring for Plant Stand: (b) (4)

Disposition of the Harvested Material: (b) (4)

General Results of Field Trial: (b) (4)

Honolulu, HI

Planting Date January 24-26, 2000

Harvest Date: April 28-May 9, 2000

OR120018_BR_012799

Destruct Date: May 15, 2000

Vector Constructs/Line Numbers Planted: (b) (4)

Purpose of trial: (b) (4)

Field Monitoring for Disease Susceptibility: (b) (4)

Field Monitoring for Insect Susceptibility: (b) (4)

Field Monitoring for Plant Growth Characteristics: (b) (4)

Field Monitoring for Plant Stand: (b) (4)

Method of Devitalization or Final Disposition of Plot Area after Harvest: (b) (4)

Disposition of the harvested material: (b) (4)

General Results of Field Trial: (b) (4)

CONFIDENTIAL

Wheat Field Test Report
USDA #99-266-02n Monsanto #99-726XRAB

AMENDED
November 19, 2002

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>	
7673	Imperial	CA	Not Planted
2147302562	Kern	CA	
7683	Honolulu	HI	

Kern County/CA (2147302562)

Planting Date: 12/08/1999

Harvest Date: 06/25/2000

Vector Constructs/Line Numbers Planted: (b) (4)] - CBI

Purpose of Field Trial: (b) (4)] - CBI

Field Monitoring Observations for Disease Susceptibility: (b) (4)

] - CBI

Field Monitoring Observations for Insect Susceptibility: (b) (4)

- CBI

Field Monitoring Observations for Plant Growth Characteristics: (b) (4)

] - CBI

Field Monitoring Observations for Weediness Characteristics: (b) (4)

- CBI

Field Monitoring Observations for Plant Stand: (b) (4)
[REDACTED] - CBI

Disposition of the Harvested Material: (b) (4) - CBI

Monitoring for Volunteer Plants: (b) (4)
[REDACTED] - CBI

Additional Comments: (b) (4) - CBI

Honolulu County/HI (7683)

Planting Date: 01/24/2000

Harvest Date: 04/28/2000

Destruct Date: 05/15/2000

Vector Constructs/Line Numbers Planted: (b) (4)
[REDACTED] - CBI

Purpose of Field Trial: (b) (4) - CBI

Field Monitoring Observations for Disease Susceptibility: (b) (4)
[REDACTED] - CBI

Field Monitoring Observations for Insect Susceptibility: (b) (4)
[REDACTED] - CBI

Field Monitoring Observations for Plant Growth Characteristics: (b) (4)
[REDACTED] - CBI

Field Monitoring Observations for Weediness Characteristics: (b) (4)
[REDACTED] - CBI

Field Monitoring Observations for Plant Stand: (b) (4)
[REDACTED] - CBI

Disposition of the Harvested Material: (b) (4) - CBI

Method of Devitalization or Final Disposition of Plot Area after Harvesting:
[REDACTED] - CBI

(b) (4)

Additional Comments:
[REDACTED] - CBI

(b) (4)

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C. Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C. Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982). *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C. Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. *Greenberg v. Food and Drug Administration*, 803 F.2d at 213, 1216-1218 (D.C. Cir. 1986); *Worthington Compressors, Inc. v. Costie*, 622 F.2d 45, 51-52 (D.C. Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. *Greenberg v. FDA*, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below*.

*In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 is such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPoint.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued. Information on the expressed trait of the genes is tantamount to

providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity and Characteristics of Donor Organisms

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification Of Physical Site And Release Location

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

Identification Of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

CBI-DELETED

Wheat Field Test Report
USDA #99-266-02n Monsanto #99-726XRAB

AMENDED
November 19, 2002

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>	
7673	Imperial	CA	Not Planted
2147302562	Kern	CA	
7683	Honolulu	HI	

Kern County/CA (2147302562)

Planting Date: 12/08/1999

Harvest Date: 06/25/2000

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Monitoring for Volunteer Plants: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Honolulu County/HI (7683)

Planting Date: 01/24/2000

Harvest Date: 04/28/2000

Destruct Date: 05/15/2000

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]



United States
Department of
Agriculture

Animal and
Plant Health
Inspection
Service

Plant Protection
and Quarantine

From:

Barbara
Director's Office,
Operational Support

Date:

6-26

To:

J. White

99-266-0211

☐ Prepare reply for DO,
DA, OA signature

☐ Reply directly,
please send me a copy

☐ Please handle

☐ For your comments

☐ Discuss with me

☐ For your information

☐ Bilateral Issue

☐ Due July 5

Remarks:

Ret - to me

Kay,

See Dianne for 1995-present

See Lidsky if he has anything
prior to '95

Jim

6/25/01

(b) (4)

TO: PPG: Barbara Kennedy

REQUESTER:

REQUEST #: FOIA-01-403

DUE TO FOIA: 7-5-01

Attached is a FOIA request for documents maintained by your office. Please conduct a thorough search for all responsive records, including files that may be kept in locations other than your office.

Please complete this page and return it with one single-sided copy of the responsive records to:

Teresa LaCovey, FOIA Office
Unit 50, Suite 4B09, Space 4A64

Requester wants info you have since 1987. According to him, 1987 is when the

DO NOT STAPLE THE DOCUMENTS.

compliance program started,

Search time* (clerical): _____

Search time* (professional): _____

*Does not include photocopying time

Review time (professional): _____

Search Conducted by:

Name	Title	Office and Phone
_____	_____	_____
_____	_____	_____
_____	_____	_____

Missing Document Explanation/Special Notes:

FOIA Liaison's Initials & Date: _____

U.S. PIRG Education Fund



National Association of State PIRGs

June 18, 2001

(01-403)

6-22-01
7-23-01

PPA
VS
Lef 6/22/01

Board of Directors

Alaska PIRG

California PIRG

Colorado PIRG

Connecticut PIRG

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New Jersey PIRG

New Mexico PIRG

New York PIRG

Ohio PIRG

Oregon State PIRG

Pennsylvania PIRG

Vermont PIRG

Washington PIRG

Wisconsin PIRG

Kim Pacheco

Assistant Director/FOIA Officer

4700 River Road, Unit 50

Riverdale, MD 20737-1232

Dear Ms. Pacheco:

This letter serves as a formal request under the Freedom of Information Act (5 U.S.C. 552) ("FOIA") for all information related to compliance infractions that have occurred relative to USDA-APHIS regulations for performance standards under notifications or permit conditions for the introduction of genetically engineered organisms. According to page 41 of the Bt-MAIZE section of the recent Council on Environmental Quality ("CEQ") and Office of Science and Technology Policy ("OSTP") document "CEQ and OSTP Assessment: Case Studies of Environmental Regulations for Biotechnology," "From 1995 through 2000, APHIS recorded a total of 63 such compliance infractions." I am requesting all information prior to the 1995-2000 time period, during 1995-2000, and since, related to these infractions, including:

1. The name of the applicant responsible for the infraction.
2. A detailed description of the infraction.
3. Information related to action taken by APHIS in response to the infraction.
4. All paperwork to and from APHIS and the institution responsible for the infraction.

Pursuant to the amendments of the FOIA (providing for a reduction or waiver of fees if it is "in the public interest because furnishing the information can be considered as primarily benefiting the public"), we request such a waiver. Members of U.S. PIRG and the general public are regularly and commonly affected by the science and practices which motivated this request. Responding to the specific criteria for a fee waiver at USDA:

1. These documents describe important information about the violation of critical regulations that protect public health and the environment, as well as describe the adequacies of the government's response to these violations.
2. These documents are important, as described above, yet are not publicly available for review.

3. These documents will be used for research on the subject of regulatory oversight of genetically engineered organisms on behalf of a non-profit organization. I will receive no commercial benefit, nor will my employer, by definition.
4. The information would likely be disseminated in a report that would be available on the web, and to the public upon request in hard copy. I can not fully determine my methods for dissemination without seeing what the document contains. My qualifications include an M.S. in environmental policy, and the release of several other reports in my capacity as an Environmental Advocate for U.S. PIRG.
5. Disclosure of a document fundamental to the oversight of genetic engineering is missing from the public domain. The level of public understanding is accordingly hampered. Dissemination would broaden that understanding significantly.

U.S. PIRG is a national non-profit, non-partisan research and advocacy organization which serves as the national office for a number of affiliated State PIRGs. The PIRGs have addressed major environmental and consumer issues for many years.

As the FOIA provides, we anticipate a response within ten to twenty days. If your office requires further assistance with this request, please do not hesitate to contact me at (b) (6), (b) (7)(C)

Sincerely,

(b) (6), (b) (7)(C)

Environmental Advocate

99-266-02N COMPLIANCE INFRACTION CHECKLIST

1. Reported within 24 hours?

☒ Yes

☐ No

2. How reported?

☒ Telephone *Monsanto personnel*

☐ E:mail

☐ Fedex

3. By *(b) (6), (b) (7)(C)*

4. Was the incident reported in a letter within 5 days?

☒ Yes

☐ No

5. If no why not?

6. Describe infraction:

a. Act of nature

☒ b. Outside of control of responsible person

c. Collaborator

d. Other (explain)

*Accidental spillage while enroute
to final destination*

(See other side)

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May 23, 2000

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Ms. Dianne Hatmaker
Biotechnology Program Operations
United States Department of Agriculture
Animal and Plant Health Inspection Service
4700 River Road
Riverdale, MD 20737

Re: USDA #99-266-02n

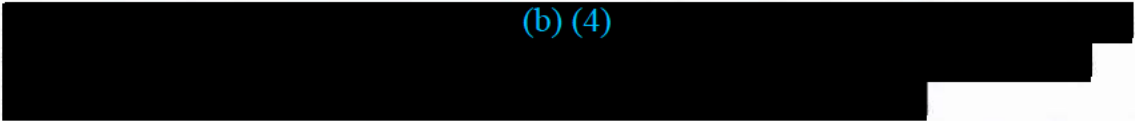
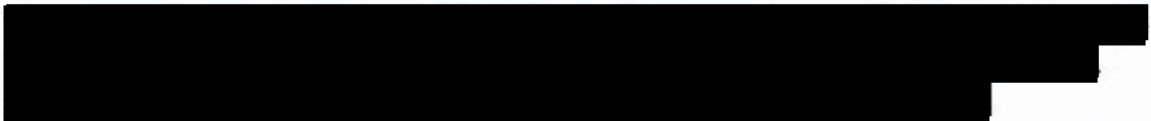
Dear Ms. Hatmaker:

(b) (4)

(b) (4)

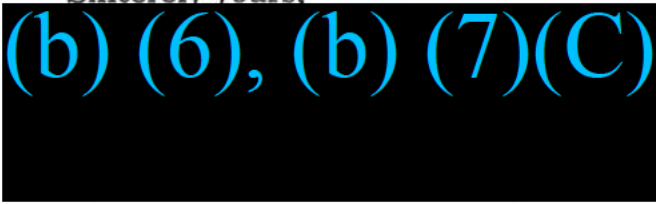
OR120018_BR_012814

(b) (4)

A large rectangular area of the document is completely blacked out, indicating redacted content.A single line of text is completely blacked out, indicating redacted content.A large rectangular area of the document is completely blacked out, indicating redacted content.A single line of text is completely blacked out, indicating redacted content.

Sincerely yours,

(b) (6), (b) (7)(C)

A rectangular area of the document is completely blacked out, indicating redacted content.

9/28/99 8:56 am

Notification Tracking Sheet

=====
Bp number: 99-266-03n
=====

App number: 99-727XRAB
Received: 9/23/99
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 10/23/99
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person: (b) (6), (b) (7)(C)
Parsed name: (b) (6), (b) (7)(C)
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: (b) (6), (b) (7)(C)
Begin movement: 10/21/99
End movement: 10/20/00
Begin release: 10/21/99
End release: 10/20/00
Acre: 8.00
CBI status: CBI
Fax: 636-737-7085
=====

- | | Initial | Date |
|--|-----------|---------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [ajb] | [9/28/99] |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist | [AMK] * | [9/29/99] * |
| 3. <input checked="" type="checkbox"/> Letter of notification to State | [KLO] | [9/29/99] * |
| 4. <input type="checkbox"/> State response | | |

O/d	Loc	Site	Reg		
Interstate	*Dest*	CA	*	*WR	*
Interstate	*Dest*	HI	*	*WR	*
Interstate	*Dest*	MO	*	*SCR	*
Interstate	*Orig*	CA	*	*WR	*
Interstate	*Orig*	HI	*	*WR	*
Interstate	*Orig*	MO	*	*SCR	*
Release	*	CA	*	2*WR	*
Release	*	HI	*	1*WR	*

- | | | |
|--|---------|----------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [ajb] | [9/29/99] |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw | [KLO] | [10/25/99] * |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [KLO] | [10/26/99] |

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID
99-727XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 20737

Sep 21, 1999

99-266-03n

1. USDA Reference Number

2. Applicant Reference Number 99-727XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis, MO

4. Duration of Introduction

Interstate Movement and Release

Oct 21, 1999 - Oct 20, 2000

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate Tolerant

Cultivar Variety Bobwhite, BW251, AC Barrie

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Monsanto Reference ID
99-727XRAB

designation of transformed line: 25397

Constructs: PV-TXGT05

genotype:

Gene of Interest

- * Promoter: CMP3/I5 -- (b) (4)] - CBI CBI
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Gene of Interest

- * Promoter: CMoVa/I5 -- [(b) (4)] - CBI CBI
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

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99-727XRAB

7. **Mode of Transformation** Particle Bombardment
8. **Introduction** Interstate Movement and Release

Ship up to 9000 pounds wheat seed before and after harvest

ORIGIN:		DESTINATION:	
CA	HI	CA	HI
MO		MO	

Ship From:

CA

* [REDACTED] (b) (4) Kern County, CA (b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)
[REDACTED], Kern County, CA (b) (6), (b) (7)(C)

* [REDACTED] (b) (4) Imperial County, CA

CONTACT: (b) (6), (b) (7)(C), (b) (4) [REDACTED]
Yuma County, AZ, (b) (6), (b) (7)(C), (b) (4)

HI

* [REDACTED] (b) (4) Honolulu County, HI
(b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4) [REDACTED]
[REDACTED], Honolulu County, HI (b) (6), (b) (7)(C), (b) (4)

MO

* [REDACTED] (b) (4) St. Louis County, MO (b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)
[REDACTED] St. Louis County, MO, (b) (6), (b) (7)(C), (b) (4)

Ship To:

CA

CONFIDENTIAL

Monsanto Reference ID
99-727XRAB

* [REDACTED] (b) (4), Kern County, CA (b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)
Kern County, CA, [REDACTED] (b) (6), (b) (7)(C), (b) (4) USA

* [REDACTED] (b) (4), Imperial County, CA

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4), Yuma
County, AZ, [REDACTED] (b) (6), (b) (7)(C), (b) (4)

HI

* [REDACTED] (b) (4), Honolulu County, HI
[REDACTED] (b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)
[REDACTED] Honolulu County, HI, [REDACTED] (b) (6), (b) (7)(C), (b) (4)

MO

[REDACTED] (b) (4), St. Louis County, MO (b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)
St. Louis County, MO, [REDACTED] (b) (6), (b) (7)(C), (b) (4) U.S.A., [REDACTED] (b) (6), (b) (7)(C), (b) (4)

Release Sites:

NUMBER OF STATES/TERRITORIES AND SITES:

CA (2) HI (1)

CA

* [REDACTED] (b) (4) Kern County, CA 1 acres.

RESPONSIBLE PERSON/RESEARCHER: [REDACTED] (b) (6), (b) (7)(C), (b) (4)
[REDACTED] Kern County, CA. Contact: [REDACTED] (b) (6), (b) (7)(C), (b) (4)

* [REDACTED] (b) (4) Imperial County, CA 2 acres.

RESPONSIBLE PERSON/RESEARCHER: [REDACTED] (b) (6), (b) (7)(C), (b) (4)
[REDACTED] Yuma County, AZ. Contact: [REDACTED] (b) (6), (b) (7)(C), (b) (4)

CONFIDENTIAL

Monsanto Reference ID
99-727XRAB

HI

* [REDACTED] (b) (4) Honolulu County, HI 5 acres.

RESPONSIBLE PERSON/RESEARCHER: [REDACTED] (b) (6), (b) (7)(C), (b) (4)
[REDACTED], Honolulu County, HI. Contact: [REDACTED] (b) (6), (b) (7)(C), (b) (4)

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID
99-727XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company
Sep 21, 1999

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential concerns the description of the gene introduced into corn and/or the variety into which they were transformed. The gene description category includes the names and information about genes, promoters and expressed traits.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many person years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of high solid, insect, fungal, and virus resistant crops for more than 10 years, and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the person hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this FOIA request, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the CBI Justification expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include Rhone-Poulenc, ICI, and Ciba-Geigy.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, And Expressed Traits

The release of information about the genes and promoters in the vectors will directly provide *competitors* with the knowledge of the *precise* genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the *competitors* will have access to the structure of the Monsanto products, with the consequences outlined above. Patents *for* the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity And Characteristics Of Donor Organism

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identity of Recipient Cultivars

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organism has been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification of Items claimed as Confidential Business Information

Items claimed as CBI as so indicated in the text as follows: [CBI - Deleted]. A non-confidential copy of the application is also included with the confidential item enclosed in brackets, "[]", as labeled as CBI.

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CBI - DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID
99-727XRAB

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 20737

Sep 21, 1999

99-266-03n

1. USDA Reference Number

2. Applicant Reference Number 99-727XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C)

FAX

636/737-7085

Monsanto Company

EMail

(b) (6), (b) (7)(C)@monsanto.com

700 Cheserfield Parkway North

St. Louis, MO

4. Duration of Introduction

Interstate Movement and Release

Oct 21, 1999 - Oct 20, 2000

5. Recipient Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar Variety Bobwhite, BW251, AC Barrie

CBI - DELETED

Monsanto Reference ID
99-727XRAB

designation of transformed line: 25397

Constructs: PV-TXGT05

genotype:

Gene of Interest

- * Promoter: CMP3/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Gene of Interest

- * Promoter: CMoVa/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI - DELETED

Monsanto Reference ID
99-727XRAB

7. Mode of Transformation Particle Bombardment

8. Introduction Interstate Movement and Release

Ship up to 9000 pounds wheat seed before and after harvest

ORIGIN:		DESTINATION:	
CA	HI	CA	HI
MO		MO	

Ship From:

CA

* [REDACTED] (b) (4), Kern County, CA (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4)
[REDACTED], Kern County, CA (b) (6), (b) (7)(C)

(b) (4), Imperial County, CA

CONTACT: (b) (6), (b) (7)(C), (b) (4)
Yuma County, AZ, (b) (6), (b) (7)(C), (b) (4)

HI

(b) (4) (b) (4), Honolulu County, HI
(b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4)
[REDACTED] Honolulu County, HI, (b) (6), (b) (7)(C), (b) (4)

MO

* [REDACTED] (b) (4), St. Louis County, MO (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4)
[REDACTED] St. Louis County, MO (b) (6), (b) (7)(C), (b) (4)

Ship To:

CA

CBI - DELETED

Monsanto Reference ID
99-727XRAB

* [REDACTED] (b) (4), Kern County, CA (b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)
Kern County, CA, [REDACTED] (b) (6), (b) (7)(C) USA

* [REDACTED] (b) (4), Imperial County, CA

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4), Yuma
County, AZ, [REDACTED] (b) (6), (b) (7)(C), (b) (4)

HI

[REDACTED] (b) (4), Aiea, Honolulu County, HI
(b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)
[REDACTED] Honolulu County, HI, [REDACTED] (b) (6), (b) (7)(C), (b) (4)

MO

* [REDACTED] (b) (4), St. Louis County, MO (b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)
St. Louis County, MO, [REDACTED] (b) (6), (b) (7)(C) U.S.A., [REDACTED] (b) (6), (b) (7)(C), (b) (4)

Release Sites:

NUMBER OF STATES/TERRITORIES AND SITES:

CA (2)

HI (1)

CA

* [REDACTED] (b) (4), Kern County, CA 1 acres.

RESPONSIBLE PERSON/RESEARCHER: [REDACTED] (b) (6), (b) (7)(C), (b) (4)
[REDACTED] Kern County, CA. Contact: [REDACTED] (b) (6), (b) (7)(C), (b) (4),

* [REDACTED] (b) (4) Imperial County, CA 2 acres.

RESPONSIBLE PERSON/RESEARCHER: [REDACTED] (b) (6), (b) (7)(C), (b) (4)
[REDACTED] Yuma County, AZ. Contact: [REDACTED] (b) (6), (b) (7)(C), (b) (4)

CBI - DELETED

Monsanto Reference ID
99-727XRAB

HI

* [REDACTED] (b) (4), Honolulu County, HI 5 acres.

RESPONSIBLE PERSON/RESEARCHER: [REDACTED] (b) (6), (b) (7)(C), (b) (4)
[REDACTED] Honolulu County, HI. Contact: [REDACTED] (b) (6), (b) (7)(C), (b) (4)

MONSANTO

Food • Health • Hope



CBI - DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID
99-727XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

Sep 21, 1999

MONSANTO

Food • Health • Hope



CBI - DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID
99-727XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 20737

Sep 21, 1999

99-266-03n

1. USDA Reference Number

2. Applicant Reference Number 99-727XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C)

FAX

636/737-7085

Monsanto Company

EMail

(b) (6), (b) (7)(C)@monsanto.com

700 Cheserfield Parkway North

St. Louis, MO

4. Duration of Introduction

Interstate Movement and Release

Oct 21, 1999 - Oct 20, 2000

5. Recipient Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar Variety Bobwhite, BW251, AC Barrie

CBI - DELETED

Monsanto Reference ID
99-727XRAB

designation of transformed line: 25397

Constructs: PV-TXGT05

genotype:

Gene of Interest

- * Promoter: CMP3/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Gene of Interest

- * Promoter: CMoVa/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI - DELETED

Monsanto Reference ID
99-727XRAB

7. Mode of Transformation Particle Bombardment

8. Introduction Interstate Movement and Release

Ship up to 9000 pounds wheat seed before and after harvest

ORIGIN:		DESTINATION:	
CA	HI	CA	HI
MO		MO	

Ship From:

CA

* [REDACTED] (b) (4), Kern County, CA (b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)
[REDACTED] Kern County, CA, (b) (6), (b) (7)(C)

* [REDACTED] (b) (4) Imperial County, CA

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)
Yuma County, AZ, (b) (6), (b) (7)(C), (b) (4)

HI

* [REDACTED] (b) (4), Honolulu County, HI
(b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)
[REDACTED] Honolulu County, HI, (b) (6), (b) (7)(C), (b) (4)

MO

* [REDACTED] (b) (4), St. Louis County, MO (b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)
[REDACTED] St. Louis County, MO (b) (6), (b) (7)(C), (b) (4)

Ship To:

CA

CBI - DELETED

Monsanto Reference ID
99-727XRAB

* [REDACTED] (b) (4), Kern County, CA (b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4),
Kern County, CA, [REDACTED] (b) (6), (b) (7)(C) USA

* [REDACTED] (b) (4), Imperial County, CA

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4), Yuma
County, AZ, [REDACTED] (b) (6), (b) (7)(C), (b) (4)

HI

[REDACTED] (b) (4) Honolulu County, HI
(b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)
[REDACTED] Honolulu County, HI, [REDACTED] (b) (6), (b) (7)(C), (b) (4)

MO

[REDACTED] (b) (4), St. Louis County, MO (b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4),
St. Louis County, MO, [REDACTED] (b) (6), (b) (7)(C) U.S.A. [REDACTED] (b) (6), (b) (7)(C), (b) (4)

Release Sites:

NUMBER OF STATES/TERRITORIES AND SITES:

CA (2) HI (1)

CA

* [REDACTED] (b) (4), Kern County, CA 1 acres.

RESPONSIBLE PERSON/RESEARCHER: [REDACTED] (b) (6), (b) (7)(C), (b) (4)
[REDACTED] Kern County, CA. Contact: [REDACTED] (b) (6), (b) (7)(C), (b) (4),

* [REDACTED] (b) (4) Imperial County, CA 2 acres.

RESPONSIBLE PERSON/RESEARCHER: [REDACTED] (b) (6), (b) (7)(C), (b) (4)
[REDACTED] Yuma County, AZ. Contact: [REDACTED] (b) (6), (b) (7)(C), (b) (4)

CBI - DELETED

Monsanto Reference ID
99-727XRAB

HI

* (b) (4), Honolulu County, HI 5 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (6), (b) (7)(C), (b) (4)
(b) (6), (b) (7)(C), (b) (4) Honolulu County, HI. Contact: (b) (6), (b) (7)(C), (b) (4)

file copy

Ms. Barbara Hass, State Regulatory Official
California Department of Food and Agriculture
1220 N Street - Rm A-372
Sacramento, CA 95814

September 28, 1999

Dear Ms. Hass:

Enclosed is notification 99-266-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-266-03n	Applicant #:	99-727XRAB
Received:	September 23, 1999	Effective:	October 23, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA HI MO		
Release destination:	CA HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012837

file copy

Mr. Myron Isherwood Jr., Manager
Plant Quarantine Branch
Hawaii Department of Agriculture
701 Ilalo Street
Honolulu, HI 96813

September 28, 1999

Dear Mr. Isherwood Jr.:

Enclosed is notification 99-266-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-266-03n	Applicant #:	99-727XRAB
Received:	September 23, 1999	Effective:	October 23, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA HI MO		
Release destination:	CA HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012838

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

September 28, 1999

Dear Mr. Brown:

Enclosed is notification 99-266-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-266-03n	Applicant #:	99-727XRAB
Received:	September 23, 1999	Effective:	October 23, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA HI MO		
Release destination:	CA HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012839



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Ms. Barbara Hass, State Regulatory Official
California Department of Food and Agriculture
1220 N Street - Rm A-372
Sacramento, CA 95814

September 28, 1999

Dear Ms. Hass:

Enclosed is notification 99-266-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-266-03n	Applicant #:	99-727XRAB
Received:	September 23, 1999	Effective:	October 23, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA HI MO		
Release destination:	CA HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Batmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination provided, wheat seed from Missouri is prohibited unless it meets the requirements of Title 3, Calif. Code of Regs., Section 3277, Cereal Leaf
____ State DOES NOT CONCUR and offers the following reasons: Beetle Exterior Quarantine.

Name of State official: Barbara J. Hass (916) 654-1017

Signature: (b) (6), (b) (7)(C)

Date: October 5, 1999

State: California



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OR120018_BR_012840

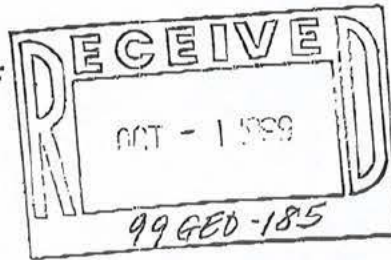


United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Myron Isherwood Jr., Manager
Plant Quarantine Branch
Hawaii Department of Agriculture
701 Ilalo Street
Honolulu, HI 96813



September 28, 1999

Dear Mr. Isherwood Jr.:

Enclosed is notification 99-266-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-266-03n	Applicant #:	99-727XRAB
Received:	September 23, 1999	Effective:	October 23, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA HI MO		
Release destination:	CA HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination. Please notify Ms. Carol Okada,
Hawaii Dept. of Agriculture, 701 Ilalo St., Honolulu, HI 96813
☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Carol L. Okada

Signature: (b) (6), (b) (7)(C)

Date: 12 October 1999

State: Hawaii



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AN Equal Opportunity Employer

OCT 14 1999

OR120018_BR_012841



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

September 28, 1999

Dear Mr. Brown:

Enclosed is notification 99-266-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-266-03n	Applicant #:	99-727XRAB
Received:	September 23, 1999	Effective:	October 23, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA HI MO		
Release destination:	CA HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: (b) (6), (b) (7)(C)

Date: 10/4/99

State: MO



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An Equal Opportunity Employer

OR120018_BR_012842

TOTAL P.07

October 25, 1999

(b) (6), (b) (7)(C)
Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3 (c), effective on or after October 25, 1999.

Interstate movement and Release
Notification no. 99-266-03n (727XRAB)
Regulated article - Wheat
Destinations - California, Hawaii, Missouri

You must comply with the performance standards as stated in 7 CFR 340.3 (c). All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

The State of California concurs with APHIS determination; provided, wheat seed from Missouri is prohibited unless it meets the requirements of Title 3, California Code of Regulations, Section 3277, Cereal Leaf Beetle Exterior Quarantine.

In addition, the State of Hawaii has requested that you adhere to the following requirements:

1. The field should remain fallow for a minimum of thirty days. During the fallow period, the field should be watered by overhead irrigation to allow the germination of volunteer wheat. Volunteer wheat should be destroyed.
2. Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 701 Ilalo Street, Honolulu, Hawaii 96813, at each of the following times:
 - a) All planting, pollinating and harvesting dates of each field trial.
 - b) Any changes to the field sites, recommended conditions, or other related matters.
 - c) The unplanned release or theft of any transgenic wheat plants or plant parts.
3. Submit a written report on the field test data including information on:

OR120018_BR_012843

- a) The germination of volunteer wheat after harvest.
- b) Pollen movement and viability under island's climatic conditions, and any occurrence of introduced traits transferred to non-test plants.

The report should be submitted to the Plant Quarantine Branch, 701 Ilalo Street, Honolulu, Hawaii, 96813, with a copy to Ms. Carol Okada, within six months of completion or termination of the test.

4. The introduction of any organism other than wheat seeds may be regulated by the Plant Quarantine Branch. For more information on the organisms regulated by the Branch, please contact Mr. Myron Isherwood Jr., Hawaii Department of Agriculture.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Biotechnology Evaluations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

B. Hass, California Dept. of Food and Agric., Sacramento, CA
M. Isherwood, Hawaii Dept. of Agric., Honolulu, HI
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
R. Stoaks, PPQ, WR, Sacramento, CA
D. DeWeese, PPQ, SCR, Jefferson City, MO
File number 99-266-03n

No CBI

Wheat Field Test Report
USDA #99-266-03n : **Monsanto #99-727XRAB**

November 14, 2002

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>	
7673	Imperial	CA	Not Planted
2147302562	Kern	CA	Not Planted
7683	Honolulu	HI	Not Planted

2/10/99 10:44 am

Notification Tracking Sheet

Bp number: 99-039-16n

App number: 99-056XRAB
Received: 2/08/99
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 3/10/99
Phenotype: HT - Glyphosate tolerant
Comments:

Begin movement: 3/07/99
End movement: 3/06/00
Begin release: 3/07/99
End release: 3/06/00
Acre: 24.00
CBI status: CBI

Resp person: (b) (6), (b) (7)(C)
Parsed name: (b) (6), (b) (7)(C)
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway North
Address3:
Address4:
City/State/Zip: St. Louis, MO 63198
Telephone: (b) (6), (b) (7)(C)

Fax: 314-737-7085

	Initial	Date
1. [✓] Assign Bp number and initial data entry	[ajd]	[2/10/99]
2. [✓] Review by biotechnologist	[KH]*	[]*
3. [✓] Letter of notification to State	[bgs]	[2/11/99]* fed x
4. [] State response		

	O/d	Loc	Site	Reg
Interstate	*Dest*CO	*	*WR	*
Interstate	*Dest*ID	*	*WR	*
Interstate	*Dest*MT	*	*WR	*
Interstate	*Dest*ND	*	*SCR	*
Interstate	*Dest*SD	*	*SCR	*
Interstate	*Dest*WA	*	*WR	*
Interstate	*Orig*MO	*	*SCR	*
Interstate	*Orig*ND	*	*SCR	*
Release	*CO	*	1*WR	*
Release	*ID	*	1*WR	*
Release	*MT	*	1*WR	*
Release	*ND	*	2*SCR	*
Release	*SD	*	1*SCR	*
Release	*WA	*	2*WR	*

5. [✓] Enter genes into database	[ajd]	[2/10/99]
6. [✓] Letter of acknowledgement/denial/withdraw	[bgs]	[2/22/99]* fed x
7. [✓] Enter final data into database	[bgs]	[2/24/99]

MONSANTO

Food • Health • Hope



CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID
99-056XRAB

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 20737

05-Feb-99

- 99-039-16n
1. **USDA Reference Number**
 2. **Applicant Reference Number** 99-056XRAB
 3. **Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

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314-737-7085

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(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company
700 Chesterfield Village Pkwy
St. Louis, MO 63198

4. **Duration of Introduction**

Interstate Movement and Release 3/7/99 - 3/6/2000

5. **Recipient** Wheat, Triticum aestivum
6. **Regulated Article**

Phenotypic Category: HT

Phenotype Glyphosate Tolerant

CONFIDENTIAL

Monsanto Reference ID
99-056XRAB

designation of transformed line: 33391, 33456, 33463

Constructs: PV-TXGT10

genotype:

Gene of Interest

* Promoter: CMP3/I5 -- (b) (4)
(b) (4)

CBI

* Gene: CTP2-CP4 -- (b) (4)

CBI

(b) (4)

* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Gene of Interest

* Promoter: CMoVa/I2 -- (b) (4)

CBI

(b) (4)

* Gene: CTP2-CP4 -- (b) (4)

CBI

(b) (4)

* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CONFIDENTIAL

Monsanto Reference ID
99-056XRAB

designation of transformed line: 31849

Constructs: PV-TXGT11

genotype:

Gene of Interest

* Promoter: CMP 3/I5 -- (b) (4)

(b) (4)

CBI

* Gene: CTP2-CP4 -- (b) (4)

(b) (4)

CBI

* Terminator: NOS 3' +2 -- (b) (4)

(b) (4)

CBI

Gene of Interest

* Promoter: CMoVa/I5 + leader1 -- (b) (4)

(b) (4)

CBI

* Gene: CTP2-CP4 -- (b) (4)

(b) (4)

CBI

* Terminator: M1 3' -- (b) (4)

(b) (4)

CBI

CONFIDENTIAL

Monsanto Reference ID
99-056XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

genotype:

Gene of Interest

* Promoter: MP4 --

(b) (4)

(b) (4)

CBI

* Gene: CTP2-CP4 --

(b) (4)

(b) (4)

CBI

* Terminator: M1 --

(b) (4)

(b) (4)

CBI

Gene of Interest

* Promoter: CMP 3/15 --

(b) (4)

(b) (4)

CBI

* Gene: CTP7-CP4 --

(b) (4)

(b) (4)

CBI

* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CONFIDENTIAL

Monsanto Reference ID
99-056XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 40 pounds of wheat seed in up to 4 shipments to each location.

ORIGIN:
MO

ND

DESTINATION:

CO

ID

MT

ND

Not

SD

WA

Ship From:

MO

(b) (4)

St. Louis County, MO (b) (4) U.S.A

ND

* (b) (4), (b) (6), (b) (7)(C)

Fargo, Cass County, ND (b) (4), (b) (6), (b) (7)(C)

Ship To:

CO

* (b) (4), (b) (6), (b) (7)(C)

(b) (4)

Weld County, CO,

(b) (4), (b) (4), (b) (6), (b) (7)(C)

ID

(b) (4), (b) (6), (b) (7)(C)

(b) (4)

Ada County, ID, (b) (4)

MT

(b) (4), (b) (6), (b) (7)(C)

(b) (4)

Cascade County, MT, (b) (4)

(b) (4), (b) (6), (b) (7)(C)

CONFIDENTIAL

Monsanto Reference ID
99-056XRAB

ND

(b) (4), (b) (6), (b) (7)(C) Cass County, ND, (b) (4), (b) (6), (b) (7)(C)

North Dakota

(b) (4), (b) (6), (b) (7)(C) (b) (4) Ward County, North Dakota U.S.A., (b) (4), (b) (6), (b) (7)(C)

SD

(b) (4), (b) (6), (b) (7)(C) Roberts County, SD, (b) (4), (b) (6), (b) (7)(C)

WA

(b) (4), (b) (6), (b) (7)(C) (b) (4) Walla Walla County, WA,
(b) (4), (b) (6), (b) (7)(C) (b) (4)

(b) (4), (b) (6), (b) (7)(C) (b) (4) Adams County, WA, (b) (4)

Release Sites:

NUMBER OF STATES/TERRITORIES AND SITES:

CO(1)
North
Dakota(1)

ID(1)
SD(1)

MT(1)
WA(2)

ND(1)

CO

* (b) (4) Weld County, CO. Contact: (b) (4), (b) (6), (b) (7)(C)

Release Location: (b) (4) Weld County, CO Up to 4 acres.

ID

* (b) (4) Ada County, ID. Contact: (b) (4), (b) (6), (b) (7)(C)

Release Location: Canyon County, ID Up to 4 acres.

MT

* (b) (4) Cascade County, MT. Contact: (b) (4), (b) (6), (b) (7)(C)

Release Location: Pondera County, MT Up to 4 acres.

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Monsanto Reference ID
99-056XRAB

ND

* (b) (4), (b) (6), (b) (7)(C) Cass County, ND (b) (4), (b) (6), (b) (7)(C)
Release Location: Cass County, ND Up to 4 acres.

North Dakota

* (b) (4) Ward County, North Dakota. Contact (b) (4), (b) (6), (b) (7)(C)
Release Location: (b) (4) Ward County, North Dakota Up to 4 acres.

SD

* (b) (4), (b) (6), (b) (7)(C) Roberts County, SD (b) (4), (b) (6), (b) (7)(C)
Release Location: Roberts County, SD Up to 4 acres.

WA

* (b) (4), (b) (6), (b) (7)(C) (b) (4) Walla Walla County, WA. Contact: (b) (4), (b) (6), (b) (7)(C)
Release Location: (b) (4) Walla Walla County, WA Up to 4 acres.

(b) (4), (b) (6), (b) (7)(C) Whitman County, WA. Contact: (b) (4), (b) (6), (b) (7)(C)
Release Location: (b) (4), (b) (6), (b) (7)(C) Whitman County, WA Up to 4 acres.

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Monsanto Reference ID
99-056XRAB

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

St. Louis, Missouri 63198

PHONE (314) 694-0000

<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company
05-Feb-99

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

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<http://www.monsanto.com>

Monsanto Reference ID
99-056XRAB

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4700 River Rd.
Riverdale, MD 20737

05-Feb-99

1. USDA Reference Number

99-039-16n

2. Applicant Reference Number

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3. Applicant/Responsible Party

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700 Chesterfield Village Pkwy N

St. Louis, MO 63198

4. Duration of Introduction

Interstate Movement and Release 3/7/99 - 3/6/2000

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype

Glyphosate Tolerant

Monsanto Reference ID
99-056XRAB

designation of transformed line: 33391, 33456, 33463

Constructs: PV-TXGT10

genotype:

Gene of Interest

- * Promoter: CMP3/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Gene of Interest

- * Promoter: CMoVa/I2 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Monsanto Reference ID
99-056XRAB

designation of transformed line: 31849

Constructs: PV-TXGT11

genotype:

Gene of Interest

- * Promoter: CMP 3/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' +2 -- [CBI Deleted]

Gene of Interest

- * Promoter: CMoVa/I5 + leader1 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: M1 3' -- [CBI Deleted]

Monsanto Reference ID
99-056XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

genotype:

Gene of Interest

- * Promoter: MP4 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: M1 -- [CBI Deleted]

Gene of Interest

- * Promoter: CMP 3/15 -- [CBI Deleted]
- * Gene: CTP7-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Monsanto Reference ID
99-056XRAB

7. **Mode of Transformation** Disarmed Agrobacterium tumefaciens

8. **Introduction** Interstate Movement and Release

Ship up to 40 pounds of wheat seed in up to 4 shipments to each location.

ORIGIN:		DESTINATION:	
MO	ND	CO	ID
		MT	ND
		Ne	SD
		WA	

Ship From:

MO

(b) (4)

St. Louis County, MO, (b) (4) J.S.A

ND

* (b) (6), (b) (7)(C), (b) (4) Cass County, ND, (b) (6), (b) (7)(C), (b) (4)

Ship To:

CO

(b) (6), (b) (7)(C), (b) (4) (b) (4) Weld County, CO,
(b) (4) (b) (6), (b) (7)(C), (b) (4)

ID

(b) (6), (b) (7)(C), (b) (4) (b) (4) Ada County, ID, (b) (4)

MT

(b) (6), (b) (7)(C), (b) (4) (b) (4) Cascade County, MT, (b) (4) (b) (6), (b) (7)(C), (b) (4)
(b) (6), (b) (7)(C), (b) (4)

ND

* (b) (6), (b) (7)(C), (b) (4) Cass County, ND, (b) (6), (b) (7)(C), (b) (4)

North Dakota

* (b) (6), (b) (7)(C), (b) (4) (b) (4) Ward County, North Dakota U.S.A., (b) (6), (b) (7)(C), (b) (4)

Monsanto Reference ID
99-056XRAB

SD

* (b) (6), (b) (7)(C), (b) (4) [REDACTED]
[REDACTED] Roberts County, SD, (b) (6), (b) (7)(C), (b) (4) [REDACTED]

WA

(b) (6), (b) (7)(C), (b) (4) [REDACTED] (b) (4) [REDACTED] Walla Walla County, WA,
99362 (b) (6), (b) (7)(C), (b) (4) [REDACTED]

(b) (6), (b) (7)(C), (b) (4) [REDACTED] (b) (4) [REDACTED] Adams County, WA, (b) (4) [REDACTED]

Release Sites:**NUMBER OF STATES/TERRITORIES AND SITES:**

CO(1)
North
Dakota(1)

ID(1)
SD(1)

MT(1)
WA(2)

ND(1)

CO

* (b) (6), (b) (7)(C), (b) (4) [REDACTED] Weld County, CO. Contact: (b) (6), (b) (7)(C), (b) (4) [REDACTED]
(b) (6), (b) (7)(C), (b) (4) [REDACTED]

Release Location: (b) (4) [REDACTED] Weld County, CO Up to 4 acres.

ID

* (b) (6), (b) (7)(C), (b) (4) [REDACTED] Ada County, ID. Contact: (b) (6), (b) (7)(C), (b) (4) [REDACTED]
(b) (6), (b) (7)(C), (b) (4) [REDACTED]

Release Location: Canyon County, ID Up to 4 acres.

MT

* (b) (6), (b) (7)(C), (b) (4) [REDACTED] Cascade County, MT. Contact: (b) (6), (b) (7)(C), (b) (4) [REDACTED]
(b) (6), (b) (7)(C), (b) (4) [REDACTED]

Release Location: Pondera County, MT Up to 4 acres.

ND

* (b) (6), (b) (7)(C), (b) (4) [REDACTED] Cass County, ND, (b) (6), (b) (7)(C), (b) (4) [REDACTED]

Release Location: Cass County, ND Up to 4 acres.

North Dakota

* (b) (6), (b) (7)(C), (b) (4) [REDACTED] Ward County, North Dakota. Contact: (b) (6), (b) (7)(C), (b) (4) [REDACTED]

Release Location: (b) (4) [REDACTED] Ward County, North Dakota Up to 4 acres.

CBI DELETED

Monsanto Reference ID
99-056XRAB

SD

* (b) (6), (b) (7)(C), (b) (4) [REDACTED] Roberts County, SD (b) (6), (b) (7)(C), (b) (4) [REDACTED]

Release Location: Roberts County, SD Up to 4 acres.

WA

* (b) (6), (b) (7)(C), (b) (4) [REDACTED] Walla Walla County, WA. Contact: (b) (6), (b) (7)(C), (b) (4) [REDACTED]
(b) (6), (b) (7)(C), (b) (4) [REDACTED]

Release Location: (b) (4) [REDACTED] Walla Walla County, WA Up to 4 acres.

* (b) (6), (b) (7)(C), (b) (4) [REDACTED] Whitman County, WA. Contact: (b) (6), (b) (7)(C), (b) (4) [REDACTED]

Release Location: (b) (6), (b) (7)(C), (b) (4) [REDACTED] Whitman County, WA Up to 4 acres.

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Monsanto Reference ID
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MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
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<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

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St. Louis, MO 63198

4. Duration of Introduction

Interstate Movement and Release 3/7/99 - 3/6/2000

5. Recipient Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype

Glyphosate Tolerant

Monsanto Reference ID
99-056XRAB

designation of transformed line: 31849

Constructs: PV-TXGT11

genotype:

Gene of Interest

- * Promoter: CMP 3/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' +2 -- [CBI Deleted]

Gene of Interest

- * Promoter: CMoVa/I5 + leader1 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: M1 3' -- [CBI Deleted]

Monsanto Reference ID
99-056XRAB

designation of transformed line: 33391, 33456, 33463

Constructs: PV-TXGT10

genotype:

Gene of Interest

- * Promoter: CMP3/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Gene of Interest

- * Promoter: CMoVa/I2 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Monsanto Reference ID
99-056XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

genotype:

Gene of Interest

- * Promoter: MP4 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: M1 -- [CBI Deleted]

Gene of Interest

- * Promoter: CMP 3/I5 -- [CBI Deleted]
- * Gene: CTP7-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Monsanto Reference ID
99-056XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 40 pounds of wheat seed in up to 4 shipments to each location.

ORIGIN:

MO

ND

DESTINATION:

CO

ID

MT

ND

Not

SD

WA

Ship From:

MO

(b) (4)

St. Louis County, MO, (b) (4) U.S.A

ND

* (b) (6), (b) (7)(C), (b) (4)

Cass County, ND, (b) (6), (b) (7)(C), (b) (4)

Ship To:

CO

* (b) (6), (b) (7)(C), (b) (4)

(b) (4)

Weld County, CO,

(b) (4) (b) (6), (b) (7)(C), (b) (4)

ID

(b) (6), (b) (7)(C), (b) (4)

(b) (4)

Ada County, ID, (b) (4)

MT

(b) (6), (b) (7)(C), (b) (4)

(b) (4)

Cascade County, MT, (b) (4)

(b) (6), (b) (7)(C), (b) (4)

ND

* (b) (6), (b) (7)(C), (b) (4)

Fargo, Cass County, ND, (b) (6), (b) (7)(C), (b) (4)

North Dakota

* (b) (6), (b) (7)(C), (b) (4)

(b) (4)

Ward County, North Dakota U.S.A.

(b) (6), (b) (7)(C), (b) (4)

Monsanto Reference ID
99-056XRAB

SD

* (b) (6), (b) (7)(C), (b) (4) [REDACTED] Roberts County, SD (b) (6), (b) (7)(C), (b) (4) [REDACTED]

WA

* (b) (6), (b) (7)(C), (b) (4) [REDACTED] (b) (4) [REDACTED] Walla Walla County, WA,
(b) (4) (b) (6), (b) (7)(C), (b) (4) [REDACTED]

(b) (6), (b) (7)(C), (b) (4) [REDACTED] (b) (4) [REDACTED] Adams County, WA, (b) (4) [REDACTED]

Release Sites:

NUMBER OF STATES/TERRITORIES AND SITES:

CO(1)	ID(1)	MT(1)	ND(1)
North	SD(1)	WA(2)	
Dakota(1)			

CO

* (b) (6), (b) (7)(C), (b) (4) [REDACTED] (b) (4) [REDACTED] Weld County, CO. Contact: (b) (6), (b) (7)(C), (b) (4) [REDACTED]

Release Location: (b) (4) [REDACTED] Weld County, CO Up to 4 acres.

ID

* (b) (6), (b) (7)(C), (b) (4) [REDACTED] (b) (4) [REDACTED] Ada County, ID. Contact: (b) (6), (b) (7)(C), (b) (4) [REDACTED]

Release Location: Canyon County, ID Up to 4 acres.

MT

* (b) (6), (b) (7)(C), (b) (4) [REDACTED] (b) (4) [REDACTED] Cascade County, MT. Contact: (b) (6), (b) (7)(C), (b) (4) [REDACTED]

Release Location: Pondera County, MT Up to 4 acres.

ND

* (b) (6), (b) (7)(C), (b) (4) [REDACTED] (b) (6), (b) (7)(C), (b) (4) [REDACTED] Cass County, ND

Release Location: Cass County, ND Up to 4 acres.

North Dakota

* (b) (4) [REDACTED] Ward County, North Dakota. Contact: (b) (6), (b) (7)(C), (b) (4) [REDACTED]

Release Location: (b) (4) [REDACTED] Ward County, North Dakota Up to 4 acres.

CBI DELETED

Monsanto Reference ID
99-056XRAB

SD

* (b) (6), (b) (7)(C), (b) (4) Roberts County, SD (b) (6), (b) (7)(C), (b) (4)

Release Location: Roberts County, SD Up to 4 acres.

WA

* (b) (4) Walla Walla County, WA. Contact: (b) (6), (b) (7)(C), (b) (4)
(b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (4) Walla Walla County, WA Up to 4 acres.

* (b) (6), (b) (7)(C), (b) (4) Whitman County, WA. Contact: (b) (6), (b) (7)(C), (b) (4) (b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (6), (b) (7)(C), (b) (4) Whitman County, WA Up to 4 acres.

MONSANTO

Food • Health • Hope



CBI DELETED

Monsanto Reference ID
99-056XRAB

MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company
05-Feb-99

file copy

Mr. Mitch Yergert
Colorado Department of Agriculture
700 Kipling Street - Suite 4000
Lakewood, CO 80215-5894

February 10, 1999

Dear Mr. Yergert:

Enclosed is notification 99-039-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-039-16n	Applicant #:	99-056XRAB
Received:	February 8, 1999	Effective:	March 10, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO ID MT ND SD WA		
Release destination:	CO ID MT ND SD WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012382

file copy

Dr. Rogelio R. Vega
Division of Plant Industries
Idaho Department of Agriculture
2270 Old Penitentiary Road
Boise, ID 83712

February 10, 1999

Dear Dr. Vega:

Enclosed is notification 99-039-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-039-16n	Applicant #:	99-056XRAB
Received:	February 8, 1999	Effective:	March 10, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO ID MT ND SD WA		
Release destination:	CO ID MT ND SD WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012383

file copy

Dr. Gary Gingery, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

February 10, 1999

Dear Dr. Gingery:

Enclosed is notification 99-039-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-039-16n	Applicant #:	99-056XRAB
Received:	February 8, 1999	Effective:	March 10, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO ID MT ND SD WA		
Release destination:	CO ID MT ND SD WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012384

file copy

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

February 10, 1999

Dear Mr. Nelson:

Enclosed is notification 99-039-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-039-16n	Applicant #:	99-056XRAB
Received:	February 8, 1999	Effective:	March 10, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO ID MT ND SD WA		
Release destination:	CO ID MT ND SD WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012385

file copy

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182

February 10, 1999

Dear Mr. Fridley:

Enclosed is notification 99-039-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-039-16n	Applicant #:	99-056XRAB
Received:	February 8, 1999	Effective:	March 10, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO ID MT ND SD WA		
Release destination:	CO ID MT ND SD WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012386

file copy

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

February 10, 1999

Dear Mr. Wessels:

Enclosed is notification 99-039-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-039-16n	Applicant #:	99-056XRAB
Received:	February 8, 1999	Effective:	March 10, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO ID MT ND SD WA		
Release destination:	CO ID MT ND SD WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012387



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Mitch Yergert
Colorado Department of Agriculture
700 Kipling Street - Suite 4000
Lakewood, CO 80215-5894

6661 21 99
February 10, 1999
RECEIVED

Dear Mr. Yergert:

Enclosed is notification 99-039-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 99-039-16n Applicant #: 99-056XRAB
Received: February 8, 1999 Effective: March 10, 1999
Institution: Monsanto Recipient: Wheat
Interstate destination: CO ID MT ND SD WA
Release destination: CO ID MT ND SD WA

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Mitchell Yergert

Signature: (b) (6), (b) (7)(C)

Date: February 12, 1999

State: Colorado



APHIS - Promoting American Agriculture

An Equal Opportunity Employer

OR120018_BR_012388

2/12/99



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Dr. Rogelio R. Vega
Division of Plant Industries
Idaho Department of Agriculture
2270 Old Penitentiary Road
Boise, ID 83712

February 10, 1999

RECEIVED

FEB 12 1999

PLANT INDUSTRIES

Dear Dr. Vega:

Enclosed is notification 99-039-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-039-16n	Applicant #:	99-056XRAB
Received:	February 8, 1999	Effective:	March 10, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO ID MT ND SD WA		
Release destination:	CO ID MT ND SD WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

(b) (6), (b) (7)(C)

Date: Feb. 16, 1999

State: IDAHO





United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MO 20737

Dr. Gary Gingery, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

February 10, 1999

Dear Dr. Gingery:

Enclosed is notification 99-039-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 99-039-16n Applicant #: 99-056XRAB
Received: February 8, 1999 Effective: March 10, 1999
Institution: Monsanto Recipient: Wheat
Interstate destination: CO ID MT ND SD WA
Release destination: CO ID MT ND SD WA

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Lori M. Witham

Signature: (b) (6), (b) (7)(C)

Date: 2/16/99

State: Montana





United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

February 10, 1999

Dear Mr. Nelson:

Enclosed is notification 99-039-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 99-039-16n Applicant #: 99-056XRAB
Received: February 8, 1999 Effective: March 10, 1999
Institution: Monsanto Recipient: Wheat
Interstate destination: CO ID MT ND SD WA
Release destination: CO ID MT ND SD WA

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination.

 State DOES NOT CONCUR and offers the following reasons:

Name of State official: DAVID R NELSON

Signature: (b) (6), (b) (7)(C)

Date: 2-12-99

State: ND

2/12/99



APHIS - Protecting American Agriculture

OR120018_BR_012001



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MO 20737

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182

February 10, 1999

Dear Mr. Fridley:

Enclosed is notification 99-039-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Ap number	99-039-16n	Applicant #:	99-056XRAB
Received:	February 8, 1999	Effective:	March 10, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO ID MT ND SD WA		
Release destination:	CO ID MT ND SD WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX



STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Kevin Fridley

Signature: (b) (6), (b) (7)(C)

Date: 2/12/99

State: South Dakota





United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

February 10, 1999

Dear Mr. Wessels:

Enclosed is notification 99-039-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-039-16n	Applicant #:	99-056XRAB
Received:	February 8, 1999	Effective:	March 10, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO ID MT ND SD WA		
Release destination:	CO ID MT ND SD WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Thomas L. Wessels

Signature: (b) (6), (b) (7)(C)

Date: 2/12/99

State: WA



2/16/99

February 22, 1999

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Village Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3 (c), effective on or after March 10, 1999.

Interstate movement and Release

Notification no. 99-039-16n (99-056XRAB)

Regulated article - Wheat

Destinations - Colorado, Idaho, Montana, North Dakota, South Dakota, Washington

You must comply with the performance standards as stated in 7 CFR 340.3 (c). In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

M. Yergert, Colorado Dept. of Agric., Lakewood, CO
R. Vega, Idaho Dept. of Agric., Boise, ID
G. Gingery, Montana Dept. of Agric., Helena, MT
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
K. Fridley, South Dakota Dept. of Agric., Pierre, SD
T. Wessels, Washington Dept. of Agric., Olympia, WA
R. Stoaks, PPQ, WR, Sacramento, CA
D. DeWeese, PPQ, SCR, Brownsville, TX

File number 99-039-16n

OR120018_BR_012394

Lotus cc:Mail For: (b) (6), (b) (7)(C)

Author: (b) (6), (b) (7)(C)
Date: 2/5/99 2:58 PM
Priority: Normal
TO: (b) (6), (b) (7)(C)
Subject: Re[3]: Notification Approval

----- Message Contents -----

(b) (4)

Reply Separator

Subject: Re[2]: Notification Approval
Author: (b) (6), (b) (7)(C)
Date: 02/05/1999 1:31 PM

(b) (6), (b) (7)(C)

I forgot to ask, what is the person's name in Tennessee that will be receiving the seed?

(b) (6), (b) (7)(C)

Reply Separator

Subject: Re: Notification Approval
Author: (b) (6), (b) (7)(C)
Date: 2/5/99 8:08 AM

(b) (6), (b) (7)(C)

This should be sent to

(b) (4)

(b) (6), (b) (7)(C)

Reply Separator

Subject: Notification Approval
Author: (b) (6), (b) (7)(C)
Date: 02/04/1999 7:42 PM

(b) (6), (b) (7)(C)

Who is the person at (b) (4) that should receive a compliance packet to ship PV-GHBK11 to the (b) (4) TN?

Thanks,

(b) (6), (b) (7)(C)

1999 Wheat Field Test Report
USDA # 99-039-16n Monsanto # 99-056XRAB
(b) (6), (b) (7)(C)
December 12, 2000

Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>
(b) (4)	Weld	CO
(b) (6), (b) (7)(C), (b) (4)	Canyon	ID (Not Planted)
(b) (4)	Pondera	MT
	Cass	ND
	Ward	ND (Not Planted)
(b) (6), (b) (7)(C), (b) (4)	Roberts	SD (Not Planted)
	Whitman	WA
(b) (4)	Walla Walla	WA

Weld County, CO

Planting Date: March 29, 1999

Harvest Date/ Destruct: June 23, 26, 1999

Vector Constructs/Line Numbers Planted: (b) (4)

(b) (4)

Purpose of Field Trial: (b) (4)

Field Monitoring for Disease Susceptibility: (b) (4)

(b) (4)

Field Monitoring for Insect Susceptibility: (b) (4)

(b) (4)

Field Monitoring for Plant Growth Characteristics: (b) (4)

(b) (4)

Field Monitoring for Weediness Characteristics: (b) (4)

(b) (4)

Monitoring for Volunteer Plants: (b) (4)

(b) (4)

Pondera County, MT

Planting Date: April 20, 1999

Harvest Date/Destruct: August 24, 1999

Vector Constructs/Line Numbers Planted:

(b) (4)

(b) (4)

Purpose of Field Trial:

(b) (4)

Field Monitoring for Disease Susceptibility:

(b) (4)

(b) (4)

Field Monitoring for Insect Susceptibility:

(b) (4)

(b) (4)

Field Monitoring for Plant Growth Characteristics:

(b) (4)

(b) (4)

Field Monitoring for Weediness Characteristics:

(b) (4)

(b) (4)

Method of Devitilization or Final Disposition of Plot area after Harvest:

(b) (4)

(b) (4)

Cass County, ND

Planting Date: May 26, 1999

Harvest Date/ Destruct: September 29, 1999

Vector Constructs/Line Numbers Planted:

(b) (4)

(b) (4)

Purpose of Field Trial:

(b) (4)

Field Monitoring for Disease Susceptibility:

(b) (4)

(b) (4)

Field Monitoring for Insect Susceptibility:

(b) (4)

(b) (4)

Field Monitoring for Plant Growth Characteristics:

(b) (4)

(b) (4)

Field Monitoring for Weediness Characteristics:

(b) (4)

(b) (4)

Monitoring for Volunteer Plants

(b) (4)

(b) (4)

Whitman County, WA

Planting Date: April 16, 1999

Destruct/Harvest: September 3, 1999

Vector Constructs/Line Numbers Planted: (b) (4)

(b) (4)

Field Monitoring for Disease Susceptibility: (b) (4)

(b) (4)

Field Monitoring for Insect Susceptibility: (b) (4)

(b) (4)

Field Monitoring for Plant Growth Characteristics: (b) (4)

(b) (4)

Field Monitoring for Weediness Characteristics: (b) (4)

(b) (4)

Method of Devitilization or Final Disposition of Plot area after Harvest: (b) (4)

(b) (4)

Monitoring for Volunteer Plants: (b) (4)

(b) (4)

Walla Walla, WA

Planting Date: April 14, 1999

Harvest Date/ Destruct : August 16, 1999

Vector Constructs/Line Numbers Planted: (b) (4)

(b) (4)

Purpose of trial: (b) (4)

Field Monitoring for Disease Susceptibility: (b) (4)

(b) (4)

Field Monitoring for Insect Susceptibility: (b) (4)

(b) (4)

Field Monitoring for Plant Growth Characteristics: (b) (4)

(b) (4)

Field Monitoring for Weediness Characteristics: (b) (4)

(b) (4)